SUBJECT NARRATIVES

Primary Reason for Narrative	Subject Number
Death	Subject C4591001 1007 10071101
	Subject C4591001 1066 10661350
	Subject C4591001 1081 10811194
	Subject C4591001 1152 11521085
	Subject C4591001 1162 11621327
	Subject C4591001 1231 12313972
Related Serious Adverse Event	Subject C4591001 1015 10151047
	Subject C4591001 1018 10181159
	Subject C4591001 1142 11421247
	Subject C4591001 1178 11781107 (also Safety-Related Subject Withdrawal)
Safety-Related Subject Withdrawal	Subject C4591001 1005 10051214
	Subject C4591001 1006 10061020
	Subject C4591001 1011 10111181
	Subject C4591001 1012 10121163
	Subject C4591001 1015 10151134
	Subject C4591001 1016 10161087
	Subject C4591001 1027 10271105
	Subject C4591001 1037 10371252
	Subject C4591001 1054 10541186
	Subject C4591001 1055 10551145
	Subject C4591001 1071 10711023
	Subject C4591001 1071 10711169
	Subject C4591001 1079 10791004
	Subject C4591001 1083 10831029
	Subject C4591001 1083 10831060

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Subject C4591001 1087 10871121
Subject C4591001 1087 10871228
Subject C4591001 1087 10871557
Subject C4591001 1090 10901415
Subject C4591001 1090 10901507
Subject C4591001 1093 10931058
Subject C4591001 1095 10951141
Subject C4591001 1095 10951173
Subject C4591001 1096 10961031
Subject C4591001 1109 11091503
Subject C4591001 1112 11121118
Subject C4591001 1112 11121255
Subject C4591001 1112 11121337
Subject C4591001 1117 11171186
Subject C4591001 1120 11201127
Subject C4591001 1120 11201408
Subject C4591001 1122 11221026
Subject C4591001 1127 11271022
Subject C4591001 1133 11331170
Subject C4591001 1134 11341153
Subject C4591001 1134 11341174
Subject C4591001 1140 11401035
Subject C4591001 1140 11401306
Subject C4591001 1142 11421111
Subject C4591001 1145 11451076
Subject C4591001 1152 11521359
Subject C4591001 1152 11521476
Subject C4591001 1152 11521497
Subject C4591001 1156 11561015
Subject C4591001 1163 11631059
Subject C4591001 1166 11661047
Subject C4591001 1205 12051028
Subject C4591001 1224 12241012
Subject C4591001 1224 12241065
Subject C4591001 1226 12261072
Subject C4591001 1230 12301045
Subject C4591001 1231 12311409
Subject C4591001 1231 12311926

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Subject C4591001 1231 12312577
Subject C4591001 1231 12312982
Subject C4591001 1231 12315429
Subject C4591001 1231 12315441
Subject C4591001 1232 12321213
Subject C4591001 1232 12321293
Subject C4591001 1241 12411279
Subject C4591001 1241 12411766
Subject C4591001 1246 12461025
Subject C4591001 1247 12471121
Subject C4591001 1247 12471135
Subject C4591001 1248 12481218
Subject C4591001 1254 12541142
Subject C4591001 1270 12701057
Subject C4591001 4444 44441979

Other Serious Adverse Event

Subject C4591001 1003 10031065
Subject C4591001 1003 10031113
Subject C4591001 1003 10031149
Subject C4591001 1005 10051054
Subject C4591001 1005 10051069
Subject C4591001 1005 10051293
Subject C4591001 1006 10061098
Subject C4591001 1007 10071276
Subject C4591001 1007 10071347
Subject C4591001 1008 10081184
Subject C4591001 1008 10081603
Subject C4591001 1009 10091135
Subject C4591001 1011 10111029
Subject C4591001 1013 10131084
Subject C4591001 1013 10131176
Subject C4591001 1013 10131517
Subject C4591001 1016 10161277
Subject C4591001 1016 10161289
Subject C4591001 1018 10181132
Subject C4591001 1019 10191010
Subject C4591001 1019 10191037

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Subject C4591001 1019 10191146
Subject C4591001 1019 10191229
Subject C4591001 1019 10191254
Subject C4591001 1021 10211190
Subject C4591001 1027 10271054
Subject C4591001 1028 10281059
Subject C4591001 1028 10281060
Subject C4591001 1038 10381101
Subject C4591001 1042 10421166
Subject C4591001 1044 10441093
Subject C4591001 1047 10471114
Subject C4591001 1054 10541173
Subject C4591001 1055 10551153
Subject C4591001 1055 10551176
Subject C4591001 1057 10571052
Subject C4591001 1057 10571137
Subject C4591001 1057 10571327
Subject C4591001 1072 10721007
Subject C4591001 1079 10791228
Subject C4591001 1079 10791246
Subject C4591001 1080 10801013
Subject C4591001 1080 10801152
Subject C4591001 1081 10811026
Subject C4591001 1081 10811036
Subject C4591001 1081 10811046
Subject C4591001 1081 10811110
Subject C4591001 1081 10811135
Subject C4591001 1082 10821076
Subject C4591001 1082 10821094
Subject C4591001 1083 10831194
Subject C4591001 1084 10841219
Subject C4591001 1084 10841317
Subject C4591001 1084 10841480
Subject C4591001 1085 10851216
Subject C4591001 1087 10871029
Subject C4591001 1087 10871070
Subject C4591001 1087 10871150
Subject C4591001 1088 10881220

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Subject C4591001 1089 10891150
Subject C4591001 1089 10891182
Subject C4591001 1090 10901300
Subject C4591001 1091 10911197
Subject C4591001 1091 10911300
Subject C4591001 1092 10921015
Subject C4591001 1092 10921123
Subject C4591001 1092 10921187
Subject C4591001 1094 10941155
Subject C4591001 1095 10951101
Subject C4591001 1095 10951107
Subject C4591001 1095 10951180
Subject C4591001 1095 10951204
Subject C4591001 1095 10951228
Subject C4591001 1096 10961044
Subject C4591001 1096 10961062
Subject C4591001 1097 10971011
Subject C4591001 1097 10971017
Subject C4591001 1097 10971025
Subject C4591001 1097 10971061
Subject C4591001 1097 10971084
Subject C4591001 1098 10981024
Subject C4591001 1107 11071044
Subject C4591001 1107 11071065
Subject C4591001 1109 11091111
Subject C4591001 1109 11091164
Subject C4591001 1109 11091204
Subject C4591001 1109 11091276
Subject C4591001 1109 11091387
Subject C4591001 1109 11091448
Subject C4591001 1109 11091558
Subject C4591001 1110 11101031
Subject C4591001 1111 11111095
Subject C4591001 1111 11111109
Subject C4591001 1111 11111130
Subject C4591001 1111 11111193
Subject C4591001 1114 11141080
Subject C4591001 1116 11161045

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Subject C4591001 1116 11161059
Subject C4591001 1117 11171036
Subject C4591001 1118 11181044
Subject C4591001 1118 11181057
Subject C4591001 1118 11181074
Subject C4591001 1124 11241106
Subject C4591001 1127 11271023
Subject C4591001 1128 11281014
Subject C4591001 1128 11281103
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Subject C4591001 1134 11341058
Subject C4591001 1134 11341250
Subject C4591001 1135 11351143
Subject C4591001 1140 11401002
Subject C4591001 1140 11401009
Subject C4591001 1140 11401078
Subject C4591001 1140 11401244
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Subject C4591001 1142 11421044
Subject C4591001 1142 11421084
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Subject C4591001 1146 11461264
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Subject C4591001 1152 11521260
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Subject C4591001 1156 11561006
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Subject C4591001 1157 11571134

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Subject C4591001 1161 11611029
Subject C4591001 1162 11621059
Subject C4591001 1167 11671009
Subject C4591001 1167 11671085
Subject C4591001 1167 11671175
Subject C4591001 1170 11701217
Subject C4591001 1174 11741042
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Subject C4591001 1178 11781025
Subject C4591001 1178 11781048
Subject C4591001 1178 11781138
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Subject C4591001 1195 11951023
Subject C4591001 1221 12211007
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Subject C4591001 1223 12231182
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Subject C4591001 1226 12261300
Subject C4591001 1226 12261571
Subject C4591001 1226 12261745
Subject C4591001 1226 12261769
Subject C4591001 1226 12262089
Subject C4591001 1226 12262240
Subject C4591001 1230 12301025
Subject C4591001 1231 12311205
Subject C4591001 1231 12311281
Subject C4591001 1231 12311315
Subject C4591001 1231 12311352
Subject C4591001 1231 12311579
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Subject C4591001 1231 12311946

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Subject C4591001 1231 12312390
Subject C4591001 1231 12312576
Subject C4591001 1231 12312593
Subject C4591001 1231 12312854
Subject C4591001 1231 12312868
Subject C4591001 1231 12312914
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Subject C4591001 1231 12313621
Subject C4591001 1231 12313653
Subject C4591001 1231 12313674
Subject C4591001 1231 12313783
Subject C4591001 1231 12314001
Subject C4591001 1231 12314035
Subject C4591001 1231 12314216
Subject C4591001 1231 12314407
Subject C4591001 1231 12314833
Subject C4591001 1231 12314898
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Subject C4591001 1231 12315632
Subject C4591001 1231 12315653
Subject C4591001 1241 12411206
Subject C4591001 1241 12411643
Subject C4591001 1241 12411825
Subject C4591001 1241 12412191
Subject C4591001 1246 12461035
Subject C4591001 1248 12481120
Subject C4591001 1248 12481163
Subject C4591001 1251 12511050
Subject C4591001 1260 12601037
Subject C4591001 1260 12601069
Subject C4591001 1261 12611006
Subject C4591001 1265 12651101
Subject C4591001 1270 12701069
Subject C4591001 4444 44441007
Subject C4591001 4444 44441249
Subject C4591001 4444 44441748

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COVID-19 Case (Evaluable and/or Severe)

Subject C4591001 1047 10471252
Subject C4591001 1116 11161253
Subject C4591001 1156 11561044
Subject C4591001 1221 12211002
Subject C4591001 1226 12261599
Subject C4591001 1226 12261624
Subject C4591001 1231 12312914
Subject C4591001 1231 12313422
Subject C4591001 1235 12351071
Subject C4591001 4444 44442304

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Table of Abbreviations		
Category	**Abbreviation**	**Text**
Action - Subject	N	No action
	O	Other
	P	Drug withdrawn (study intervention discontinued)
	TC	Concomitant drug treatment given
	TCN	Concomitant non-drug treatment given
	W	Withdrawn from study
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
	GENRL	General disorders and administration site conditions
	HEPAT	Hepatobiliary disorders
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PREG	Pregnancy, puerperium and perinatal conditions
	PSYCH	Psychiatric disorders
	RENAL	Renal and urinary disorders
	REPRO	Reproductive system and breast disorders

Table of Abbreviations		
Category	**Abbreviation**	**Text**
	RESP	Respiratory, thoracic and mediastinal disorders
	SKIN	Skin and subcutaneous tissue disorders
	SOCCI	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.5 cm	129.6 kg	46.2 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2000	Present
Sleep apnea	Sleep apnoea syndrome	2013	Present
Gastroesophageal reflux	Gastrooesophageal reflux disease	2018	Present
Gastric sleeve	Gastrectomy	SEP2019	Past
Supraventricular tachycardia	Supraventricular tachycardia	08OCT2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30JUL2020 (1)	13:11
2	BNT162b2	20AUG2020 (22)	11:45

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Cardiac arrest	Cardiac Arrest	18OCT2020 (81)		21OCT2020 (84)		4	4	W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Fatal (21OCT2020)	NOT RELATED/OTHER: Heart attack. Occurred 2 months after last receipt of study agent	2	60	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	17SEP2020	
Withdrawn	FOLLOW-UP	21OCT2020	DEATH

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Narrative Comment
Subject C4591001 1007 10071101, a 56-year-old white female with pertinent medical history of obesity (since 2000), sleep apnea syndrome (since 2013), and supraventricular tachycardia (on 08 Oct 2019), received Dose 1 on 30 Jul 2020 and Dose 2 on 20 Aug 2020 (Day 22). The subject died because of cardiac arrest on 21 Oct 2020, 62 days after receiving Dose 2. On 18 Oct 2020 (Day 81), the subject presented to the emergency room following an intubation at home after a cardiac arrest. Her electrocardiogram was abnormal with initial rhythm of pulseless electrical activity and ischemic changes. The down time was reported as 15 minutes. On the same day (Day 81), a computed tomogram of the head showed cerebral edema. Emergency department spoke with cardiology who deferred an intervention and a targeted temporal management (TTM) was ordered. The laboratory results on 18 Oct 2020 (Day 81) showed blood chloride 124 mEq/L (normal range [NR]: 98 - 111 mEq/L), blood glucose 393 mg/dL (NR: 70 - 99 mg/dL), blood potassium of 3.5 mEq/L (NR: 3.6 - 5.1 mEq/L), blood sodium of 155 mEq/L (NR: 135 - 145 mEq/L), carbon dioxide of 18 mmol/L (NR: 21 - 31 mmol/L), and glomerular filtration rate of 58 mL/minute/1.73 m2 (NR: >59 mL/minute/1.73 m2). The subject was admitted to the intensive care unit and was intubated along with the pressors. On 19 Oct 2020 (Day 82), the subject was on TTM with high urine output overnight, which was concerning for diabetes insipidus. On the same day (Day 82), the subject's troponin I was high at 491 ng/L (NR: <15 ng/L), that was considered critical. The SARS CoV-2 test was negative. On 20 Oct 2020 (Day 83), a magnetic resonance imaging showed anoxic brain injury and possible herniation and an electroencephalogram showed absent brain activity. On the same day (Day 83), the subject was rewarmed. On 21 Oct 2020 (Day 84), the subject was pronounced dead at 1859 hours due to a cardiac arrest. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention or clinical trial procedures, as the death occurred 2 months after receiving Dose 2. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	84.23 kg	25.1 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
sulfa allergy	Drug hypersensitivity	1980	Present
morphine allergy	Drug hypersensitivity	1985	Present
anxiety	Anxiety	1990	Present
GERD	Gastrooesophageal reflux disease	2000	Present
hypertension	Hypertension	2000	Present
insomnia	Insomnia	2000	Present
L4-L5 laminotomy with diskectomy	Spinal laminectomy	2012	Past
spinal stenosis	Spinal stenosis	2012	Past
hyponatremia	Hyponatraemia	2015	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
history of seizure	Seizure	2015	Past
history of alcohol abuse	Alcohol abuse	2018	Past
cardiomyopathy	Cardiomyopathy	MAR2018	Present
myocardial infarction	Myocardial infarction	MAR2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19OCT2020 (1)	13:32

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Myocardial infarction	myocardial infarction	03NOV2020 (16)		03NOV2020 (16)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	P/W	Y	Fatal (03NOV2020)	NOT RELATED/OTHER: disease progression	1	16	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19OCT2020	
Withdrawn	VACCINATION	03NOV2020	DEATH
Withdrawn	FOLLOW-UP	03NOV2020	DEATH

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Narrative Comment
Subject C4591001 1066 10661350, a 58-year-old white male with a pertinent medical history of hypertension (since 2000), gastroesophageal reflux disease (since 2000), insomnia (since 2000), hyponatremia (since 2015), seizures (in 2015), alcohol abuse (from 2010 to 2018), myocardial infarction (in Mar 2018), and cardiomyopathy (coronary angiography, left ventriculography, and left heart catheterization; since Mar 2018), received Dose 1 on 19 Oct 2020. The subject died because of a myocardial infarction on 03 Nov 2020, 15 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of myocardial infarction included omeprazole (Protonix) for gastroesophageal reflux disease (since 2015), trazodone for insomnia (since 2015), Depade and acamprosate calcium (Campral) for alcohol dependence (since 2018), and levetiracetam (Keppra) for seizures (since 2018). When the subject did not return for Visit 2 on 09 Nov 2020 (Day 22), the subject's wife was contacted on the same day and she stated that the subject suffered a heart attack and died in his sleep on 03 Nov 2020 (Day 16). An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medication, or clinical trial procedures, but rather it was related to disease progression. Pfizer concurred with the investigator's causality assessment and additionally considered that the myocardial infarction was mostly coincidental and associated with underlying cardiac conditions.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	95.82 kg	34 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	1995	Present
Allergy to Sulfa drugs	Drug hypersensitivity	2002	Present
Allergy to oral NSAIDs	Drug hypersensitivity	2007	Present
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2015	Present
Hypertension	Hypertension	2015	Present
Attention deficit disorder	Attention deficit hyperactivity disorder	2017	Present
Osteoarthritis of the knees	Osteoarthritis	2018	Present
Postmenopausal	Postmenopause	2018	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	12:44
2	Placebo	29SEP2020 (20)	13:39

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Death	Death	01NOV2020 (53)		01NOV2020 (53)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (01NOV2020)	NOT RELATED/OTHER: Unknown cause of death at this time	2	34	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
Withdrawn	FOLLOW-UP	01NOV2020	DEATH

Narrative Comment

Subject C4591001 1081 10811194, a 51-year-old white female with a medical history of hypothyroidism (since 1995), drug hypersensitivity (allergy to sulfa drugs since 2002 and allergy to oral NSAIDs since 2007), chronic obstructive pulmonary disease and hypertension (both since 2015), attention deficit hyperactivity disorder (since 2017), and osteoarthritis and postmenopause (both since 2018), received Dose 1 on 10 Sep 2020 and Dose 2 on 29 Sep 2020 (Day 20).

The subject was scheduled for her convalescent visit on 11 Nov 2020 but did not show up for her appointment. The family was contacted and it was reported that the subject was found deceased in her home on 04 Nov 2020 and likely died 3 days prior. A family member had spoken with the subject on 01 Nov 2020 and the subject told her family member that she just got out of the shower and was going to go lay down due to having “stomach pains”. This was the final conversation with the subject before she died. No autopsy was performed. A copy of the death certificate was requested. The cause of death was reported as unknown.

In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator’s causality assessment, and considered that the death was not related to concomitant medications and was most likely coincidental and associated with underlying clinical conditions.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	84.09 kg	28.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
chronic sinusitis	Chronic sinusitis	2000	Present
seasonal allergies	Seasonal allergy	2000	Present
breast cancer	Breast cancer	2001	Past
lumpectomy left breast	Breast conserving surgery	2001	Past
breast cancer	Breast cancer	2017	Past
lumpectomy left breast	Breast conserving surgery	2017	Past

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Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	19AUG2020 (1)	10:38

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GENRL	Unevaluable event	Unknown of Unknown Origin	26AUG2020 (8)		26AUG2020 (8)		1	4

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	P/W	Y	Fatal (26AUG2020)	NOT RELATED/OTHER: Waiting on death certificate	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	26AUG2020	DEATH
Withdrawn	FOLLOW-UP	26AUG2020	DEATH

Narrative Comment

Subject C4591001 1152 11521085, a 42-year-old white female with a pertinent medical history of recurrent breast cancer (in 2001 and 2017) and lumpectomy (left breast; in 2001 and 2017) and implantation of an Essure permanent birth control device (implanted in 2017), received Dose 1 on 19 Aug 2020. The subject was not taking any concomitant medications.

The subject's husband stated that the subject had no adverse events after receiving Dose 1. She had a normal evening and went to bed on 25 Aug 2020 (Day 7). By the next morning (26 Aug 2020), the subject had died (Day 8). An autopsy was performed and the results are still pending at the time of this report.

In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention. The investigator further stated that although the full autopsy report was pending and determining cause of death at this time was essentially an educated guess, the subject had possible risk factors. She possibly had a thromboembolic event related to a history of breast cancer, or there was a potential toxicity related to the Essure permanent birth control device. Essure implant for permanent birth control was taken off the market in the United States by the Food and Drug Administration (FDA) in 2018. A brief review revealed almost 50,000 reports to the FDA regarding the device and approximately 50 deaths. Pfizer commented that there was not enough evidence to suggest a causal relationship between the study intervention and the subject's death.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.5 cm	100.4 kg	32.6 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
autoimmune thyroiditis	Autoimmune thyroiditis	2010	Present
overweight/obese	Obesity	2010	Present
traumatic brain injury	Craniocerebral injury	2011	Past
depression	Depression	2011	Present
hip replacement	Hip arthroplasty	2015	Past
reading glasses	Corrective lens user	2017	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	12:09

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Arteriosclerosis	Atherosclerotic Disease	13SEP2020 (4)		13SEP2020 (4)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (13SEP2020)	NOT RELATED/OTHER: underlying disease	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Withdrawn	VACCINATION	13SEP2020	DEATH
Withdrawn	FOLLOW-UP	13SEP2020	DEATH

Narrative Comment
Subject C4591001 1162 11621327, a 60-year-old white male with a pertinent medical history of obesity (since 2010), traumatic brain injury (in 2011, recovered), depression (since 2011), and hip replacement (in 2015), received Dose 1 on 10 Sep 2020. The subject died of arteriosclerosis on 13 Sep 2020, 3 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of arteriosclerosis included venlafaxine hydrochloride (from 2015) and aripiprazole (from 2011), both for depression. The study site received a police report indicating that the police visited the subject's home to perform a welfare check on 13 Sep 2020 (Day 4) and found him dead. It was reported that the subject's body was cold and had visible lividity. According to the medical examiner, the probable cause of death was progression of atherosclerotic disease. Relevant tests were unknown. Autopsy results were not available at the time of this report. In the opinion of the investigator, there was no reasonable possibility that the arteriosclerosis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to suspected underlying disease. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	61 kg	22.7 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	03MAR2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	16:20
2	Placebo	13SEP2020 (20)	15:00

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Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Haemorrhagic stroke	Hemorrhagic stroke	27SEP2020 (34)	09:00	28SEP2020 (35)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/W	Y	Fatal (28SEP2020)	NOT RELATED/OTHER: unknown	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Withdrawn	VACCINATION	28SEP2020	DEATH
Withdrawn	FOLLOW-UP	28SEP2020	DEATH

Narrative Comment
Subject C4591001 1231 12313972, a 61-year-old white female with a pertinent medical history of hypertension (since 2017), received Dose 1 on 25 Aug 2020 and Dose 2 on 13 Sep 2020 (Day 20). The subject was diagnosed with a hemorrhagic stroke on 27 Sep 2020, 14 days after receiving Dose 2. Concomitant medication reported within 2 weeks before the onset of the hemorrhagic stroke included losartan (since 2017) for arterial hypertension. On 27 Sep 2020 (Day 34), the subject contacted the medical team complaining of a severe headache and incoercible vomiting, and she was advised to call the emergency system. The subject arrived at the emergency room unconscious (unknown Glasgow score) on the same day (Day 34) with nonreactive intermediate pupils and requiring life support measures including invasive mechanical ventilation and pharmacological support (inotropics, unknown drugs and doses). The subject's son informed the site that the subject was admitted to the intensive care unit at the hospital. A computed tomography of the brain on the same day (Day 35) showed subarachnoid hemorrhage, intraventricular hemorrhage, and right cerebral hemisphere hematoma (Fisher Scale 4). A brain angiography showed cerebral circulatory arrest, and therefore the location of the aneurysm could not be established. Per protocol, a PCR SAR-COV-2 swab test was performed and the results were negative. The subject did not respond to life support measures and died of hemorrhagic stroke on 28 Sep 2020 (Day 35). In the opinion of the investigator, there was no reasonable possibility that the hemorrhagic stroke was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment and considered the hemorrhagic stroke as most likely related to the subject's underlying arterial hypertension.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	65.91 kg	26.5 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Migraines	Migraine	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	17:01
2	BNT162b2	09SEP2020 (24)	15:20

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Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	EYE	Corneal irritation	Right corneal irritation	17AUG2020 (1)	22:54	20AUG2020 (4)		4
2	GENRL	Shoulder injury related to vaccine administration	SIRVA - shoulder injury related to vaccine administration	09SEP2020 (24)	18:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (20AUG2020)	NOT RELATED/OTHER: Contact lens wear	1	1	N
2	3	N	Y	Yes	Study Treatment	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1015 10151047, a 30-year-old Asian female with no pertinent medical history, received Dose 1 on 17 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 24), both in her left deltoid. The subject experienced a shoulder injury related to vaccine administration (SIRVA) on 09 Sep 2020 (Day 24), on the same day as Dose 2. Concomitant medication reported within 2 weeks before the onset of the shoulder injury included cetirizine hydrochloride for allergies (since an unknown date). On 09 Sep 2020 (Day 24), late in the evening, the subject experienced pain in the left arm. She noted that the bandage from Dose 2 was very high on her arm and experienced some soreness of her upper arm with very limited range of motion for the first few days and burning pain down her arm. Initially, she also had a tingling sensation down her arm; however, this resolved. On 15 Sep 2020 (Day 30), the subject had a sensation of numbness, which affected her arm and hand, with a sensation of loss of dexterity, notable when typing. The subject reported that her condition was improving gradually, especially in terms of pain, but she still had a significant limitation in range of motion and daily activities. On examination, she had no obvious swelling, color change, bruising, or tenderness over the left deltoid. She could raise her left arm slightly higher than 90 degrees and with assistance could lift higher, but this caused significant discomfort; she could not extend her left arm behind her back well. The strength was noted to be 5/5. When moving her arm against resistance, she experienced pain down her arm and increased sensation of numbness. The principal investigator (PI) reported a possible diagnosis of shoulder injury related to vaccine administration that was considered an important medical event. The subject was aware that the shoulder injury could be self-limited but could last for some time; however, she was hopeful that it would resolve soon and was considering physical therapy as an option. The PI suggested a neurology consultation and also discussed arrangements for physical therapy. The subject was seen by a neurologist who noted the following findings: motor function had normal muscle bulk and tone. No apparent fasciculations or scapular winging were noted. Shoulder abduction was limited to 70 degrees, shoulder internal rotation limited as well but she was able to extend her left hand behind her back. The neurologist considered 2 diagnoses: SIRVA and IPBN, noting that the clinical picture demonstrated components of both. An electromyography (EMG) was recommended to determine if there was nerve involvement and if so, to what degree. At the time of the neurological evaluation, the subject had started physical therapy. On 02 Oct 2020 (Day 47), a needle EMG of the left upper extremity for all muscles was performed and reported to be unremarkable. The deltoid sample was not collected due to the suspected prior injury to the area. It was reported that since onset, both the pain and limitation in range of motion had improved at this time; additionally, there was great improvement in the shoulder and upper arm but less so in the hand or fingers. The EMG results did not reveal any neurophysiological evidences of a left brachial plexopathy, median dysfunction at the left wrist, ulnar dysfunction across the left elbow, or left cervical radiculopathy. On 07 Oct 2020 (Day 52), the neurologist considered SIRVA as the diagnosis was mostly likely based on the clinical improvement and the EMG result that did not reveal nerve involvement. The subject reported continued improvement especially of the upper arm with increased range of motion but continued to experience decreased dexterity of the left hand. The subject was attending physical therapy twice weekly and reported satisfaction with the gradual and continued improvement. On 03 Nov 2020, the subject informed that 5 weeks of physical therapy had been completed and that the improvement was significant. The shoulder injury was ongoing at the time of the last available report. In the opinion of the investigator, there was a reasonable possibility that the SIRVA was related to the study intervention and to a clinical trial procedure (vaccine administration), but not related to concomitant medications. Pfizer concurred with the investigator's causality assessment. Additionally, it was reported that the vaccine was erroneously administered into or near the shoulder joint capsule. As postulated in the medical literature, unintentional injection of vaccines into the shoulder joint synovial tissues may result in an immune-mediated inflammatory reaction causing SIRVA.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	62.27 kg	19.9 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obstructive breathing due to deviated septum	Nasal septum deviation	(b) (6) 1967	Past
benign cyst removed	Cyst removal	1993	Past
Fibrocystic Breast Disease	Fibrocystic breast disease	1993	Past
Migraines once or twice a month	Migraine	2008	Present
Rhinoplasty	Rhinoplasty	2008	Past
Breast augmentation	Mammoplasty	2010	Past
Vitamin D deficiency	Vitamin D deficiency	2013	Past
right shoulder dislocation	Joint dislocation	2014	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Right Shoulder Repair	Shoulder operation	2014	Past
Rhinoplasty	Rhinoplasty	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	11:33
2	BNT162b2	04SEP2020 (22)	16:07

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1			Lower back pain and bilateral lower extremity pain with radicular paresthesia	20OCT2020 (68)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	TC	Y	Yes	Study Treatment	2	47	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1018 10181159, a 53-year-old white female with a pertinent medical history of osteopenia (dates unknown), vitamin D deficiency (from 2013 to 2014), vitamin B12 deficiency, migraine and neck pain (both since 2008), joint dislocation (right shoulder) and shoulder operation (both in 2014), and occipital neuralgia (since 2014), received Dose 1 on 14 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 22). The subject had lower back pain and bilateral lower extremity pain with radicular paresthesia on 20 Oct 2020, 46 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the lower back pain and bilateral lower extremity pain with radicular paresthesia included zolmitriptan (since 2008) for migraines and vitamin D NOS (since 2013) for vitamin D deficiency.

Narrative Comment
On 07 Oct 2020 (Day 55), at Visit 3, the subject reported feeling fine. On 20 Oct 2020 (Day 68), she began having back and leg pain. On 28 Oct 2020 (Day 76), she had a nasal/sinus operation and received codeine phosphate/paracetamol for 3 days. On 02 Nov 2020 (Day 81), she had lower back pain and bilateral lower extremity pain that was described as shooting pain worse on the right side. Her legs and parietal area of the scalp were sensitive to touch with an associated burning pain. She also reported tenderness in the bilateral inguinal area. The symptoms had gradually developed over approximately past 3 weeks. The subject's spine magnetic resonance imaging (Oct 2020) was unremarkable; and the subject did not consult her primary care physician or a neurologist at this time. She denied any neurological or lower back problems and any other vitamin deficiencies. The subject stated that when she began experiencing the symptoms, her pain score was assessed as 8-9 on a scale of 10 for a couple of weeks and she did not use any analgesics. She also reported that there had been a significant decrease in her level of activity. On 10 Nov 2020 (Day 89), during a follow-up visit with the investigator the subject reported that the paresthesia and skin sensitivity over the parietal area had improved. The subject reported that she used paracetamol, ibuprofen, and codeine phosphate/paracetamol initially, and later received celecoxib for neck pain. After treatment with analgesics, her pain score at its worst was 6-7 on a scale of 10. She continued to use analgesics daily and was able to function adequately despite persistence of mild (1-2/10 in severity) constant pain in her lower back and legs. The subject also reported that she had not noticed any exacerbating factors and denied any recent injury, travel, infection, or change in diet. On 10 Nov 2020 (Day 89), the subject reported that she walked approximately one mile without any problem. Despite still not having an official diagnosis, the investigator had opted to report this as an important medical event since symptoms had persisted and the subject believed they started closer to 5 weeks after vaccination, which was close to the 4 week post-vaccination observation period. The site obtained the medical records from the neurologist and the subject was seen on 06 Nov 2020 (Day 85). As per the neurologist's note, magnetic resonance imaging (MRI) of cervical spine performed several years before showed mild degenerative changes and spondylosis. The MRI of lumbar spine performed recently showed "degenerative discopathy with small left central disc protrusion at T5-T6 with minimal indentation thecal sac. No spinal cord compression, spinal canal stenosis, or neural foramina narrowing was observed. Multilevel hypertrophic changes of the facets within the lumbar spine with no neural foramina stenosis was noted. Incidental finding revealed multilevel small hemangiomas in the cervical and thoracic vertebral bodies". A neurological examination on the same day (Day 85) was normal including gait and tandem walk. Tenderness was noted in lower extremities musculature bilaterally throughout and large mobile inguinal lymph node palpable bilaterally. The laboratory tests ordered by neurologist were normal including vitamin B12: 635 pg/mL (normal range [NR]: 200 - 960 pg/mL), folate: 19.6 µg/L (NR: ≥6.0 µg/L), vitamin D 25-hydroxy: 33 ng/mL (NR: 30 - 100 ng/mL), total creatine phosphokinase: 45 U/L (NR: 28 - 176 U/L), erythrocyte sedimentation rate: 15 mm/hour (NR: 0 - 20 mm/hour), C-reactive protein: 0.3 mg/dL (NR: <0.5 mg/dL), serum aldolase: 3.9 U/L (NR: 1.5 - 7.2 U/L), thyroid stimulating hormone: 1.130 µIU/mL (NR: 0.400 - 4.100 µIU/mL), free thyroxine: 1.42 ng/dL (NR: 0.80 - 1.90 ng/dL), lyme antibody: 0.25 (negative less than 0.9); antinuclear antibody was negative, serum protein electrophoresis was normal, and no monoclonal protein was seen. Imaging study reports not available; neurologist impression included possible post-viral syndrome or an autoimmune process. There was no mention of concern for myelitis or any plan for further work-up. Neurologist's recommendation was to continue celecoxib, as needed and follow-up with primary care physician if labs were unrevealing. It was planned to have the subject return to clinic to obtain more in depth history and possibly some labs as well as request reports of MRIs. The lower back pain and bilateral lower extremity pain with radicular paresthesia was ongoing at the time of last available report. In the opinion of the investigator, there was a reasonable possibility that the lower back pain and bilateral lower extremity pain with radicular paresthesia were related to the study intervention, but not related to concomitant medications or clinical trial procedures. Pfizer did not concur with the investigator's causality assessment and considered that there is not enough evidence to establish a causal relationship with the study vaccine apart from a chronological association at this time of the report. Based on the information currently available, it was more likely that the lower back pain and bilateral lower extremity pain with radicular paresthesia was associated with the subject's underlying known neurological conditions.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	71	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	60.09 kg	22 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergy to penicillin	Drug hypersensitivity	1970	Present
breast cancer	Breast cancer	1992	Past
(R) breast reconstruction	Breast reconstruction	1992	Past
(R) mastectomy	Mastectomy	1992	Past
Atrioventricular block, complete	Atrioventricular block complete	1996	Present
Cardiac pacemaker in situ	Cardiac pacemaker insertion	1996	Present
Sinoatrial Node Dysfunction	Sinus node dysfunction	27JUN2012	Present
Paroxysmal Atrial Fibrillation	Atrial fibrillation	08APR2015	Present
Paroxysmal supraventricular tachycardia	Supraventricular tachycardia	11MAY2015	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	10:03
2	BNT162b2	14OCT2020 (24)	15:16

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	CARD	Ventricular arrhythmia	Ventricular arrhythmias	14OCT2020 (24)		21OCT2020 (31)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	8	3	TC	Y	Resolved (21OCT2020)	Study Treatment	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1142 11421247, a 71-year-old white female, with a pertinent medical history of complete atrioventricular block and cardiac pacemaker insertion (both since 1996), sinus node dysfunction (since 27 Jun 2012), atrial fibrillation (since 08 Apr 2015), and supraventricular tachycardia (since 11 May 2015), received Dose 1 on 21 Sep 2020 and Dose 2 on 14 Oct 2020 (Day 24). The subject experienced ventricular arrhythmia on 14 Oct 2020, on the same day as Dose 2. Concomitant medications reported within 2 weeks prior to the onset of ventricular arrhythmia included fluticasone propionate (since 30 Jun 2010) and cetirizine hydrochloride (since 03 Nov 2010) both for allergic rhinitis, atorvastatin (since 22 Feb 2013) for hyperlipidemia, duloxetine hydrochloride (since 17 Sep 2014), metoprolol succinate (since 08 Apr 2015) for paroxysmal supraventricular tachycardia, apixaban (since 28 Dec 2015) for atrial fibrillation, and alendronate sodium (since 03 Sep 2019) for osteoporosis. On the evening of 14 Oct 2020 (Day 24), the subject experienced a 4-beat episode of ventricular tachycardia (VT). At 2308 hours, the subject's pacemaker recorded non-sustained ventricular tachycardia (NSVT) with an average heart rate of 134 beats per minute (bpm) lasting 8 seconds. On 15 Oct 2020 (Day 25), in the morning, the subject reported a 2-beat episode. At 0956 hours, the pacemaker recorded NSVT with average heart rate of 199 bpm lasting 15 seconds. On 16 Oct 2020 (Day 26) at 1854 hours, the pacemaker recorded NSVT with an average heart rate of 164 bpm lasting 9 seconds. On 17 Oct 2020 (Day 27) at 1308 and 1322 hours, the subject had 2 episodes of NSVT with average heart rates of 185 bpm and 194 bpm lasting 9 seconds and 8 seconds, respectively. On 18 Oct 2020 (Day 28) at 1308 hours, the subject had an episode of NSVT with average heart rate of 174 bpm lasting 9 seconds. The subject reported fatigue and general malaise during the NSVT episodes. On 20 Oct 2020 (Day 30), the subject reported that she experienced subsequent episodes of ventricular tachycardia every day since the second vaccination; therefore, her cardiologist recommended a defibrillator placement. The investigator considered the ventricular arrhythmia as serious and an important medical event. Relevant laboratory test results on 21 Oct 2020 (Day 31) included troponin I of 0.016 ng/mL (normal range [NR]: 0-0.034 ng/mL), creatine kinase (CK) of 98 U/L (NR: 33-194 U/L), CK-MB of 2.76 ng/mL (NR: 0-3.50 ng/mL), CK-MB index of 2.8% (NR: 0%-2.5%), sodium of 140 mmol/L (NR: 135-145 mmol/L), potassium of 4.5 mmol/L (NR: 3.5-5.0 mmol/L), chloride of 104 mmol/L (NR: 98-108 mmol/L), carbon dioxide of 26 mmol/L (NR: 23-31 mmol/L), and anion gap of 10 (NR: 2-16; units not reported). According to her cardiologist, the CK-MB index result was within acceptable limits and the other test results were also normal. The ventricular arrhythmia was considered resolved on 21 Oct 2020 (Day 31). On 27 Oct 2020 (Day 37), the COVID-19 polymerase chain reaction molecular test and SARS-CoV-2 IgG antibody test results were negative. An electrophysiology study on 29 Oct 2020 (Day 39) showed no evidence of sustained VT/pmVT/VF; however, brief paroxysms of pmVT were seen "with aggressive phase of electrical stimulation protocol at 400/260/200/200", which was nonspecific. No indication for an implantable cardioverter-defibrillator was observed. In the opinion of the investigator, there was a reasonable possibility that the ventricular arrhythmia was related to the study intervention based on the temporal relationship since the arrhythmias began within 24 hours of Dose 2, but not related to concomitant medications or clinical trial procedures. Pfizer did not concur with the investigator's causality assessment. Additionally, Pfizer commented that there was not enough evidence to establish a causal relationship with the study intervention apart from a chronological association at this time of the report. In absence of evidence for an inflammatory response to study intervention, it was more likely that the ventricular arrhythmia was associated with the subject's underlying known cardiac conditions.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	113.64 kg	36.9 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1977	Present
sinus headache	Sinus headache	1977	Present
pitocin allergy	Drug hypersensitivity	1998	Present
benign paroxysmal vertigo	Vertigo positional	1998	Present
menorrhagia	Menorrhagia	2003	Past
uterine fibroids	Uterine leiomyoma	2003	Past
hysterctomy	Hysterectomy	2005	Past
osteoarthritis, bilateral knees and feet	Osteoarthritis	2015	Present
eczema	Eczema	2017	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	13:38

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	chills	05SEP2020 (2)	18:00	05SEP2020 (2)	20:00
2	GENRL	Injection site erythema	injection site redness	04SEP2020 (1)	19:00	05SEP2020 (2)	19:00
3	GENRL	Injection site pain	injection site muscle soreness	04SEP2020 (1)	19:00	06SEP2020 (3)	
4	GENRL	Injection site warmth	injection site warmth	04SEP2020 (1)	19:00	05SEP2020 (2)	19:00
5	BLOOD	Lymphadenopathy	right axilla lymphadenopathy	16SEP2020 (13)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	TC	N	Resolved (05SEP2020)	Study Treatment	1	2	N
2	2	1	N	N	Resolved (05SEP2020)	Study Treatment	1	1	N
3	3	2	N	N	Resolved (06SEP2020)	Study Treatment	1	1	N
4	2	1	N	N	Resolved (05SEP2020)	Study Treatment	1	1	N
5		2	TC/P	Y	Yes	Study Treatment	1	13	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Withdrawn	VACCINATION	25SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1178 11781107, a 48-year-old white female with a pertinent medical history of drug hypersensitivity to Pitocin, received Dose 1 on 04 Sep 2020 in her left deltoid. The subject was diagnosed with lymphadenopathy on 16 Sep 2020, 12 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the onset of the event included cetirizine hydrochloride (since 2015) for seasonal allergies, ibuprofen (since 2000) for headache and osteoarthritis, and crisaborole (since 2017) for eczema. On 04 Sep 2020 (Day 1), approximately 6 hours after Dose 1 administration, the subject reported mild injection site erythema and warmth, and moderate injection site pain. On 05 Sep 2020 (Day 2), she reported mild chills. That same day (Day 2), the injection site erythema, warmth, and chills were considered resolved, and on 06 Sep 2020 (Day 3), the injection site pain resolved. On 21 Sep 2020 (Day 18), the subject called and reported discomfort in her right arm, shoulder, and chest region on 16 Sep 2020 (Day 13), which she described as feeling like a pulled muscle even at rest. She was treated with ibuprofen 400 mg orally as needed starting on 16 Sep 2020. Additionally, the subject reported that she had called her physician, who referred her to the regional hospital emergency room (ER) for further evaluation. On 20 Sep 2020 (Day 17), the subject visited the ER, at which time her right axilla was examined, and a subsequent ultrasound of the right axilla on the same day revealed at least 4 enlarged lymph nodes, largest 2.5 × 1.1 × 2.4 cm. The laboratory results on the same day showed a white blood cell count of 7.0 k/µL (NR: 4.0 - 10.0 k/µL) with 35.2% lymphocytes (normal range [NR]: 20% - 40%), and an absolute lymphocyte count of 2.4 k/µL (NR: 1.0 - 4.0 k/µL). The subject denied any injuries, cuts, or puncture wounds to the right arm or having a similar problem previously. It was reported that no other areas other than the right axilla were assessed for lymphadenopathy. The subject received ketorolac 10 mg intravenously once (on 20 Sep 2020) while in the ER for lymphadenopathy. The lymphadenopathy was considered medically significant by the investigator. The biopsy was completed on 05 Oct 2020 (Day 32) without issue. On 12 Oct 2020, the subject communicated via phone the results of her work-up stating that her blood tests returned to normal and the biopsy showed no markers for lymphoma or other cancer. Per subject report, the oncologist considered the vaccine as the most likely etiology for her lymphadenopathy. A follow-up oncological visit is planned in 3 months with a possible repeat of the axillary ultrasonogram. The medical records have been requested by the investigator. The subject was discontinued from the study intervention on 25 Sep 2020 because of the lymphadenopathy that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the lymphadenopathy was related to the study intervention. Pfizer did not concur with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	110.82 kg	37.1 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MENOPAUSE	Menopause	1994	Present
HIGH CHOLESTEROL	Blood cholesterol increased	2000	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2000	Present
HIGH BLOOD PRESSURE	Hypertension	2000	Present
SWELLING OF FEET	Peripheral swelling	2000	Present
DEPRESSION	Depression	2015	Present
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2018	Present
TYPE II DIABETES	Type 2 diabetes mellitus	FEB2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	15:14

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Facial pain	FACIAL TENDERNESS	06SEP2020 (4)		16SEP2020 (14)		11	2	TC/P	N
2	GENRL	Injection site pain	INJECTION SITE PAIN	04SEP2020 (2)		07SEP2020 (5)		4	2	N	N
3	GENRL	Swelling face	FACIAL SWELLING	06SEP2020 (4)		16SEP2020 (14)		11	2	TC/P	N
4	INFEC	Upper respiratory tract infection	UPPER RESPIRATORY INFECTION	06SEP2020 (4)		16SEP2020 (14)		11	2	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (16SEP2020)	NOT RELATED/OTHER: ALLERGIC REACTION TO UNKNOWN AGENT	1	4	Y
2	Resolved (07SEP2020)	Study Treatment	1	2	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	Resolved (16SEP2020)	NOT RELATED/OTHER: ALLERGIC REACTION TO UNKNOWN AGENT	1	4	Y
4	Resolved (16SEP2020)	NOT RELATED/OTHER: CONCURRENT ILLNESS	1	4	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03SEP2020	
Withdrawn	VACCINATION	13SEP2020	ADVERSE EVENT
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1005 10051214, a 71-year-old white female with no pertinent medical history, received Dose 1 on 03 Sep 2020. On 04 Sep 2020 (Day 2), the subject experienced moderate injection site pain that resolved on 07 Sep 2020 (Day 5) and facial pain and swelling that began on 06 Sep 2020, 3 days after receiving Dose 1. The facial pain and facial swelling resolved on 16 Sep 2020 (Day 14). The subject was discontinued from the study intervention on 13 Sep 2020 because of the facial pain and facial swelling and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the facial pain and facial swelling were related to the study intervention, but rather they were related to an allergic reaction to an unknown agent.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	80.45 kg	24 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
FACTOR 5 LIDEN	Coagulation factor V level	(b) (6) 1944	Present
RECURRENT PEPTIC ULCER	Peptic ulcer	1980	Present
DEEP VEIN THROMBOPHLEBITIS RIGHT LEG	Deep vein thrombosis	1983	Present
CORONARY ARTERY DISEASE	Coronary artery disease	1989	Present
MITRAL VALVE PROLAPSE	Mitral valve prolapse	1989	Past
CORONARY ATHEROSCLEROSIS	Arteriosclerosis coronary artery	DEC1989	Present
HEART ATTACK	Myocardial infarction	DEC1989	Past
LEFT BACK PAIN	Back pain	1990	Present
DIABETES TYPE 2	Type 2 diabetes mellitus	21AUG1995	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2000	Present
RECURRENT BILATERAL LOWER EXTREMITIES EDEMA	Oedema peripheral	2000	Present
CARDIAC STENT PLACEMENT	Coronary arterial stent insertion	25MAR2004	Past
HEART ATTACK	Myocardial infarction	25MAR2004	Past
FLATULENCE	Flatulence	2008	Present
CAUTERIZED ULCERS ON DUODENUM	Duodenal ulcer repair	09FEB2008	Past
BOWEL BLOCKAGE	Intestinal obstruction	01APR2008	Past
BOWEL BLOCKAGE REMOVAL	Intestinal operation	01APR2008	Past
BASAL CELL CARCINOMA, RECURRENT, MULTIPLE LOCATIONS	Basal cell carcinoma	2010	Present
CATARACT SURGERY	Cataract operation	AUG2010	Past
XEROSIS CUTIS	Dry skin	2015	Present
POLYNEUROPATHY, DIABETIC BILATERAL FEET	Diabetic neuropathy	2016	Present
PLANTAR FACIITIS OF RIGHT FOOT	Plantar fasciitis	2016	Present
TRANSIENT ISCHEMIC ATTACK	Transient ischaemic attack	JAN2016	Past
RIGHT BUNDLE BRANCH BLOCK	Bundle branch block right	2017	Present
CARDIAC STENT PLACEMENT	Coronary arterial stent insertion	MAR2017	Past
HEART ATTACK	Myocardial infarction	MAR2017	Past
ANAL FISSURE	Anal fissure	2018	Present
HYPERTENSION	Hypertension	2018	Present
TRANSIENT ISCHEMIC ATTACK	Transient ischaemic attack	JUL2018	Past
CARDIOVASCULAR ACCIDENT	Cardiovascular disorder	06MAR2019	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	11:32

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Acute myocardial infarction	NON-ST ELEVATED MYOCARDIAL INFARCTION	25AUG2020 (14)		27AUG2020 (16)		3	3	TC/TCN
2	CARD	Angina pectoris	ANGINA	21AUG2020 (10)		27AUG2020 (16)		7	2	TCN
3	CARD	Coronary artery occlusion	CORONARY ARTERY OCCLUSION	25AUG2020 (14)		27AUG2020 (16)		3	4	TC/TCN/P/W
4	RESP	Dyspnoea exertional	DYSPNEA ON EXERTION	25AUG2020 (14)		27AUG2020 (16)		3	2	TCN
5	CARD	Mitral valve incompetence	MITRAL VALVE REGURGITATION	25AUG2020 (14)		27AUG2020 (16)		3	3	TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (27AUG2020)	NOT RELATED/OTHER: CORONARY ARTHEROSCLEROSIS	1	14	N
2	N	Resolved (27AUG2020)	NOT RELATED/OTHER: CORONARY ATHEROSCLEROSIS	1	10	N
3	Y	Resolved (27AUG2020)	NOT RELATED/OTHER: CORONARY ATHEROSCLEROSIS	1	14	Y

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Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
4	N	Resolved (27AUG2020)	NOT RELATED/OTHER: CORONARY ATHEROSCLEROSIS	1	14	N
5	N	Resolved (27AUG2020)	NOT RELATED/OTHER: PROGRESSION OF MYXOMATOUS MITRAL VALVE	1	14	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Withdrawn	VACCINATION	16SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	16SEP2020	ADVERSE EVENT

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Narrative Comment
Subject C4591001 1006 10061020, a 75-year-old white male with a pertinent medical history of factor V Leiden (since (b) (6) 1944), deep vein thrombosis (since 1983), coronary artery disease (since 1989), mitral valve prolapse (in 1989), myocardial infarction (in Dec 1989, on 25 Mar 2004, and in Mar 2017), coronary arterial stent insertion (on 25 Mar 2004 and in Mar 2017), type 2 diabetes (since 21 Aug 1995), hypercholesterolemia (since 2000), transient ischemic attack (in Jan 2016 and in Jul 2018), right bundle branch block (since 2017), hypertension (since 2018), and cardiovascular accident (on 06 Mar 2019), received Dose 1 on 12 Aug 2020. The subject was diagnosed with angina and acute myocardial infarction due to coronary artery occlusion on 25 Aug 2020, 13 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the onset of the coronary artery occlusion included warfarin (since 2005) for factor V Leiden; metformin (since 2010), insulin aspart (since 2019), and insulin glargine (since Feb 2019), all for type 2 diabetes; atorvastatin calcium (since 2018) for hypercholesterolemia; and lisinopril (since 2018) for hypertension. On 21 Aug 2020 (Day 10), the subject reported a nonserious adverse event of angina pectoris. On 25 Aug 2020 (Day 14), the subject presented to the emergency room (ER) reporting shortness of breath, for which he was admitted to the hospital with chief complaints of exertional dyspnea (reported as a nonserious adverse event) and angina with little exertion that did not abate as usual. In the ER, the subject received enoxaparin 80 mg subcutaneously once and atorvastatin 40 mg orally once daily. A chest x-ray showed no evidence of acute cardiopulmonary disease. An electrocardiogram (ECG) showed previously diagnosed right bundle branch block with ST depression in II and T-wave inversion in leads I, Vl, and aVF and inferior infarct of undetermined age with no ST elevation; the subject had an elevated troponin level of 0.84 ng/mL (normal range [NR]: 0 – 0.15 ng/mL). He was diagnosed with acute myocardial infarction (reported as a nonserious adverse event). Additional laboratory values included an elevated glucose level (value not reported) and a prothrombin time of 20.6 seconds (NR: 12.2 – 15.5 seconds). Other laboratory results included brain natriuretic peptide, fibrin D-dimer, complete blood count, and lipase, which were within normal limits (values not provided). No COVID-19 testing was performed. That same day (Day 14), the subject was also diagnosed with mitral valve incompetence (reported as a nonserious adverse event). On 26 Aug 2020 (Day 15), an angiogram was performed, which showed worsening of coronary artery disease and severe multivessel coronary artery occlusion. The coronary artery disease was considered life-threatening. The subject was given vitamin K and, on 27 Aug 2020 (Day 16), he underwent a coronary artery bypass graft, during which the mitral valve was repaired. The subject was treated with Cardene, albumin 250 mg, and epinephrine 0.03 µg/kg/min but was quickly weaned off. On 27 Aug 2020 (Day 16), the exertional dyspnea, angina pectoris, coronary artery occlusion, acute myocardial infarction, and mitral valve incompetence were considered resolved. The subject was discharged from the hospital on an unknown date. The subject was withdrawn from the study on 16 Sep 2020 because of the coronary artery occlusion. In the opinion of the investigator, there was no reasonable possibility that the coronary artery occlusion was related to the study intervention, concomitant medications, or clinical trial procedures, but rather related to coronary atherosclerosis. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	85.45 kg	32.3 kg/m2	08OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08OCT2020 (1)	14:40

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Paraesthesia	Tingling at finger tips	08OCT2020 (1)	15:15	08OCT2020 (1)	16:15
2	GASTR	Paraesthesia oral	Tingling around the mouth	08OCT2020 (1)	15:15	08OCT2020 (1)	16:14

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	N	N	Resolved (08OCT2020)	Study Treatment	1	1	N
2	1	1	P	N	Resolved (08OCT2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08OCT2020	
Withdrawn	VACCINATION	08OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1011 10111181, a 57-year-old white female with no reported medical history, received Dose 1 on 08 Oct 2020. The subject experienced oral paresthesia on 08 Oct 2020, on the same day as Dose 1. On 08 Oct 2020 (Day 1), the subject also experienced paresthesia of fingertips. On the same day (Day 1), the oral paresthesia and paresthesia of fingertips resolved. The subject was discontinued from the study intervention on 08 Oct 2020 because of the oral paresthesia and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the oral paresthesia was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	63.18 kg	20.5 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cat Scratch Disease	Cat scratch disease	1982	Present
Penicillin Allergy (Anaphylactic Shock)	Anaphylactic shock	1984	Present
Codeine Allergy	Drug hypersensitivity	1984	Present
Allergic Atopic Dermatitis	Dermatitis atopic	2016	Present
Iodine Allergy	Iodine allergy	2017	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	09SEP2020 (1)	16:58

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site dermatitis	LEFT UPPER ARM DERMATITIS AT INJECTION SITE	11SEP2020 (3)		ONGOING	
2	PSYCH	Insomnia	INSOMNIA	12SEP2020 (4)		ONGOING	
3	INV	Weight decreased	WEIGHT LOSS	14SEP2020 (6)		04OCT2020 (26)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	P/W	N	Yes	Study Treatment	1	3	Y
2		2	TC	N	Yes	Study Treatment	1	4	N
3	21	3	N	N	Resolved (04OCT2020)	Study Treatment	1	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Withdrawn	VACCINATION	24SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	17OCT2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1012 10121163, a 41-year-old white female with a pertinent medical history of atopic dermatitis (since 2016), received Dose 1 on 09 Sep 2020. The subject experienced injection site dermatitis on 11 Sep 2020, 2 days after receiving Dose 1. The subject was discontinued from the study intervention on 24 Sep 2020 because of the injection site dermatitis and subsequently was withdrawn from the study on 17 Oct 2020 because of injection site dermatitis. The injection site dermatitis was ongoing as of the last available report. In the opinion of the investigator, there was a reasonable possibility that the injection site dermatitis was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	75 kg	22.4 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Childhood asthma	Childhood asthma	1975	Present
Acid reflux	Gastrooesophageal reflux disease	2000	Present
Vertigo	Vertigo	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27AUG2020 (1)	14:39

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Diarrhoea	Diarrhea	28AUG2020 (2)		28AUG2020 (2)	
2	NERV	Headache	Headache	28AUG2020 (2)		01SEP2020 (6)	
3	GASTR	Nausea	Nausea	28AUG2020 (2)		01SEP2020 (6)	
4	EAR	Vertigo	Worsening and continuing episode of Veritgo	28AUG2020 (2)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	N	N	Resolved (28AUG2020)	Study Treatment	1	2	N
2	5	1	N	N	Resolved (01SEP2020)	Study Treatment	1	2	N
3	5	1	N	N	Resolved (01SEP2020)	Study Treatment	1	2	N
4		2	P	N	Yes	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Fluzone Quadrivalent	INFLUENZA VACCINE INACT SPLIT 4V	28SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Withdrawn	VACCINATION	06NOV2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1015 10151134, a 55-year-old white male with a pertinent medical history of vertigo (since 2012), received Dose 1 on 27 Aug 2020. The subject experienced worsening and continuing episodes of vertigo on 28 Aug 2020, 1 day after receiving Dose 1. On 28 Aug 2020 (Day 2), the subject also experienced diarrhea, headache, and nausea. The diarrhea resolved on the same day (Day 2) and the headache and nausea resolved on 01 Sep 2020 (Day 6). The subject was discontinued from the study intervention on 06 Nov 2020 because of the worsening and continuing vertigo that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the worsening and continuing vertigo was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	43	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	77.32 kg	24.4 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	APR1994	Present
allergy to flagyl	Drug hypersensitivity	APR2002	Present
meniscus repair	Meniscus operation	JUL2009	Past
migraines	Migraine	APR2010	Present
ovarian fibroid	Ovarian fibroma	JAN2015	Past
hysterectomy	Hysterectomy	JUN2015	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10AUG2020 (1)	10:35

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site swelling	injection site swelling	10AUG2020 (1)		19AUG2020 (10)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	10	3	TC/P	N	Resolved (19AUG2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Withdrawn	VACCINATION	31AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1016 10161087, a 43-year-old white female with no pertinent medical history, received Dose 1 on 10 Aug 2020. On the same day (Day 1), the subject reported severe injection site swelling, after receiving Dose 1. The injection site swelling resolved on 19 Aug 2020 (Day 10). The subject was discontinued from the study intervention on 31 Aug 2020 because of the injection site swelling and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the injection site swelling was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.47 cm	65.45 kg	24.1 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Migraine Headaches	Migraine	1995	Present
Allergy to Shellfish	Food allergy	1996	Present
Allergy to Iodine	Iodine allergy	1996	Present
Mitral Valve Prolapse	Mitral valve prolapse	2007	Present
Hypertension	Hypertension	2012	Present

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Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	28AUG2020 (1)	15:00

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	IMMUN	Allergy to vaccine	Allergic Reaction to Study Vaccine	29AUG2020 (2)		11SEP2020 (15)		14
2	MUSC	Back pain	Lower back pain	08SEP2020 (12)		11SEP2020 (15)		4
3	MUSC	Back pain	Mid back pain	11SEP2020 (15)		14SEP2020 (18)		4
4	GENRL	Chest pain	Left-sided chest pain	08SEP2020 (12)		08SEP2020 (12)		1
5	GASTR	Gastrooesophageal reflux disease	GERD	08SEP2020 (12)		ONGOING		
6	NERV	Hypoaesthesia	Right arm numbness	11SEP2020 (15)		11SEP2020 (15)		1
7	MUSC	Muscular weakness	Right leg weakness	10SEP2020 (14)		10SEP2020 (14)		1
8	RESP	Pharyngeal swelling	Throat Swelling	29AUG2020 (2)		08SEP2020 (12)		11

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC/P	N	Resolved (11SEP2020)	Study Treatment	1	2	Y
2	1	N	N	Resolved (11SEP2020)	NOT RELATED/OTHER: GERD	1	12	N
3	1	N	N	Resolved (14SEP2020)	NOT RELATED/OTHER: GERD	1	15	N
4	1	TC	N	Resolved (08SEP2020)	NOT RELATED/OTHER: Gerd	1	12	N
5	1	TC	N	Yes	NOT RELATED/OTHER: acid reflux	1	12	N

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	1	N	N	Resolved (11SEP2020)	NOT RELATED/OTHER: Unknown	1	15	N
7	2	TCN	N	Resolved (10SEP2020)	NOT RELATED/OTHER: Unknown	1	14	N
8	2	TC	N	Resolved (08SEP2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Withdrawn	VACCINATION	11SEP2020	ADVERSE EVENT
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1027 10271105, a 46-year-old black or African American female with a pertinent medical history of allergy to shellfish and iodine (since 1996), received Dose 1 on 28 Aug 2020. The subject developed pharyngeal swelling considered to be an allergic reaction to the vaccine on 29 Aug 2020, 1 day after receiving Dose 1. The allergic reaction resolved on 11 Sep 2020 (Day 15). The subject was discontinued from the study intervention on 11 Sep 2020 because of the allergic reaction and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the allergic reaction was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183 cm	107.3 kg	32 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OBESITY	Obesity	2010	Present
GASTROESPPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	01AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	12:09
2	BNT162b2	13OCT2020 (23)	10:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1			FATIGUE	14OCT2020 (24)		15OCT2020 (25)		2
2			FEVER	14OCT2020 (24)		15OCT2020 (25)		2
3			MUSCLE ACHES	14OCT2020 (24)		15OCT2020 (25)		2
4	GASTR	Nausea	Nausea	07OCT2020 (17)		07OCT2020 (17)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	P	N	Resolved (15OCT2020)	Study Treatment	2	2	Y
2	1	N	N	Resolved (15OCT2020)	Study Treatment	2	2	N
3	1	N	N	Resolved (15OCT2020)	Study Treatment	2	2	N
4	1	N	N	Resolved (07OCT2020)	NOT RELATED/OTHER: UNK	1	17	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1037 10371252, a 59-year-old black or African American male with a pertinent medical history of obesity (since 2010), received Dose 1 on 21 Sep 2020 and Dose 2 on 13 Oct 2020 (Day 23). The subject reported fatigue on 14 Oct 2020, 1 day after receiving Dose 2. On 14 Oct 2020 (Day 24), the subject also reported fever and muscle aches. The fatigue, fever, and muscle aches resolved on 15 Oct 2020 (Day 25). At the time of the data snapshot (17 Nov 2020) this subject was erroneously reported as having withdrawn from the study intervention because of the fatigue. The subject continues in the study. The data have since been corrected, which will be reflected in the next data snapshot. In the opinion of the investigator, there was a reasonable possibility that the fatigue was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	84.35 kg	28.3 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lactose intolerance	Lactose intolerance	2016	Present
appendectomy	Appendicectomy	14FEB2017	Past
appendicitis	Appendicitis	14FEB2017	Past
cyst, R axilla	Cyst	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	12:32

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Dizziness	lightheadedness	23SEP2020 (1)	12:40	23SEP2020 (1)	14:40
2	GASTR	Nausea	nausea	23SEP2020 (1)	12:40	23SEP2020 (1)	14:40

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	P	N	Resolved (23SEP2020)	Study Treatment	1	1	Y
2	1	1	P	N	Resolved (23SEP2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Withdrawn	VACCINATION	23SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1054 10541186, a 71-year-old black or African American female with no pertinent medical history, received Dose 1 on 23 Sep 2020. The subject experienced dizziness and nausea on 23 Sep 2020, after receiving Dose 1, which resolved on the same day. The subject was discontinued from the study intervention on 23 Sep 2020 because of the dizziness and nausea and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the dizziness and nausea were related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	89 kg	32.3 kg/m2	28AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	14:35

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Cerebral capillary telangiectasia	Cerebral Capillary telangiectasia	26SEP2020 (30)		ONGOING			1
2	GASTR	Dysphagia	Dysphagia	AUG2020 ()		ONGOING			1
3	MUSC	Pain in extremity	Right upper extremity pain	10OCT2020 (44)		ONGOING			1

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Yes	NOT RELATED/OTHER: anatomical abnormality	1	30	N
2	P	N	Yes	NOT RELATED/OTHER: unknown, GI or neurological abnormality			Y
3	N	N	Yes	NOT RELATED/OTHER: Cause is being evaluated	1	44	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Withdrawn	VACCINATION	14OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1055 10551145, a 35-year-old white female with no reported medical history, received Dose 1 on 28 Aug 2020. The subject experienced dysphagia on an unknown date in Aug 2020. The subject was discontinued from the study intervention on 14 Oct 2020 because of the dysphagia that was ongoing at the time of last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the dysphagia was related to the study intervention, but rather it was related to unknown GI or neurological abnormality.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.7 cm	100.7 kg	33.8 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PARTIAL HYSTERECTOMY	Hysterectomy	2012	Past
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2013	Present
HYPERTENSION	Hypertension	2015	Present
TYPE II DIABETES	Type 2 diabetes mellitus	2016	Present
CONGESTIVVE HEART FAILURE	Cardiac failure congestive	2017	Present
ALLERGIC RHINITIS	Rhinitis allergic	2017	Present
STROKE	Cerebrovascular accident	2019	Past
CORONARY ARTERY DISEASE	Coronary artery disease	2019	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	JAN2019	Present

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Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BILATERAL LEG EDEMA	Oedema peripheral	JAN2019	Present
BILATERAL ANKLE EDEMA	Oedema peripheral	JUN2019	Present
VISION LOSS	Blindness	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	12:15

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Coronary artery disease	WORSENING coronary artery disease	23AUG2020 (12)		ONGOING			2	TCN/P/W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Hypertensive cardiovascular disease or arteriosclerotic heart disease	1	12	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Withdrawn	VACCINATION	23AUG2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	28AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1071 10711023, a 56-year-old black or African American female with a pertinent medical history of hypertension (since 2015), congestive cardiac failure (since 2017), hypercholesterolemia (since Jan 2019), cerebrovascular accident (in Feb 2020), and coronary artery disease (since 2019 with 6 coronary stents placed in Sep 2019), received Dose 1 on 12 Aug 2020. The subject was diagnosed with worsening coronary artery disease on 23 Aug 2020, 11 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the onset of the worsening coronary artery disease included omeprazole (since 2010) for gastroesophageal reflux disease, sacubitril/valsartan sodium hydrate (since Jan 2018) and isosorbide dinitrate and clopidogrel (both since 2018) for congestive heart failure, acetylsalicylic acid (since 2018) for cardiovascular prophylaxis, cyanocobalamin (since 2018) as a nutritional supplement, metformin (since 2018) and empagliflozin (since Jan 2020) for type 2 diabetes, fexofenadine (since 2018) for allergic rhinitis, atorvastatin (since Jan 2019) for hypercholesterolemia, metoprolol (since Jan 2019) for hypertension, and spironolactone (since Jan 2019) and furosemide (since Jun 2019) both for edema. On 19 Aug 2020 (Day 8), at 0950 hours, the subject reported she was being evaluated for blocked stents in the hospital. During this conversation, the subject stated that she was informed by her cardiologist on 17 Aug 2020 (Day 6) that she would have her stents examined on 18 Aug 2020 (Day 7). On 18 Aug 2020 (Day 7), the subject went to the emergency room at 1700 hours and was admitted for testing; however, she was unsure about why the procedures became inpatient procedures. She reported that this planned visit to a cardiologist resulted in an overnight hospitalization. On 21 Aug 2020 (Day 10), the subject stated that previously she was never in the hospital overnight and was at the hospital only for a stress test. The site staff requested the medical records to verify the stress test. On a subsequent date, the staff spoke with the subject again regarding medical records needed for the stress test. The subject said that she had quadruple bypass surgery on 24 Aug 2020 (Day 13) for coronary artery disease, was currently in the hospital, and would be discharged the next day (31 Aug 2020). In addition, the subject reported that she had been exercising 5 times per week before the coronavirus disease (COVID) outbreak. She switched to walking daily since the COVID outbreak, and noticed getting easily winded since Jun 2020; therefore, she visited her doctor, who performed a stress test on 17 Aug 2020 (Day 6). According to the subject, her doctor called her back later that week and told her she needed surgery. The medical records were received and reviewed, which confirmed the details of the tests performed and the surgery; it was noted that a stress test was not performed on 18 Aug 2020 (Day 7), but rather an angiogram was performed; the results were not available. The subject was discontinued from the study intervention on 23 Aug 2020 because of the worsening coronary artery disease and was withdrawn from the study on 28 Aug 2020. On 31 Aug 2020, the subject recovered from the worsening coronary artery disease. According to the medical records her postoperative course was unremarkable, she recovered, and was discharged. In the opinion of the investigator, there was no reasonable possibility that the worsening coronary artery disease was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was due to hypertensive cardiovascular disease or arteriosclerotic heart disease. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	77.1 kg	24.4 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ECZEMA	Eczema	1970	Present
ALCOHOL ABUSE	Alcohol abuse	1982	Present
DEPRESSION	Depression	1982	Present
DRUG ABUSE	Drug abuse	1982	Present
SEIZURE DISORDER	Seizure	1986	Present
ALLERGIC RHINITIS	Rhinitis allergic	2013	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2015	Present
ATAXIA	Ataxia	2018	Present
CHOLELITHIASIS	Cholelithiasis	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HEPATOSTEATOSIS	Hepatic steatosis	2018	Present
PERIPHERAL NEUROPATHY BILATERAL FEET	Neuropathy peripheral	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	16:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Alcohol poisoning	ACUTE ALCOHOL INTOXICATION	02OCT2020 (18)		15OCT2020 (31)		14	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	P/W	Y	Resolved (15OCT2020)	NOT RELATED/OTHER: ALCOHOL DEPENDENCE	1	18	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15SEP2020	
Withdrawn	VACCINATION	15OCT2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	15OCT2020	ADVERSE EVENT

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Narrative Comment
Subject C4591001 1071 10711169, a 56-year-old white male with a pertinent medical history of alcohol abuse, drug abuse, and depression (all since 1982), seizures (since 1986), and ataxia, hepatic steatosis, and peripheral neuropathy (all since 2018), received Dose 1 on 15 Sep 2020. The subject was diagnosed with alcohol poisoning on 02 Oct 2020, 17 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of alcohol poisoning included loratadine (since 2013) for allergic rhinitis and levetiracetam (since Mar 2019) for a seizure disorder. On 02 Oct 2020 (Day 18), the subject went to the emergency room because of acute alcohol intoxication and was hospitalized. It was reported that the subject had a history of alcohol intake since he was a teenager and had a grand mal seizure in 2015 due to alcohol intake. On 15 Oct 2020 (Day 31), the alcohol poisoning resolved and the subject was discharged from the hospital to a rehabilitation facility. The subject was withdrawn from the study on 15 Oct 2020 because of the alcohol poisoning. In the opinion of the investigator, there was no reasonable possibility that the alcohol poisoning was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to alcohol dependence. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.2 cm	61.05 kg	25.7 kg/m2	29JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	1986	Present
IBS-M	Irritable bowel syndrome	1998	Present
Insomnia	Insomnia	1999	Present
Allergic Rhinitis - Seasonal	Seasonal allergy	2010	Present
GERD	Gastrooesophageal reflux disease	2012	Present
Hypothyroidism	Hypothyroidism	2012	Present
Fibromyalgia	Fibromyalgia	2017	Present
Cholelithiasis - Gallstones	Cholelithiasis	28JUL2020	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hydronephrosis	Hydronephrosis	28JUL2020	Present
Ovarian cyst	Ovarian cyst	28JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29JUL2020 (1)	14:35

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Adenocarcinoma gastric	INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	20AUG2020 (23)	12:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	P/W	Y	Yes	NOT RELATED/OTHER: n/a	1	23	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	29JUL2020	
Withdrawn	VACCINATION	20AUG2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	27AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1079 10791004, a 48-year-old white female with a pertinent medical history of irritable bowel syndrome (since 1998) and gastroesophageal reflux disease (since 2012), received Dose 1 on 29 Jul 2020. The subject was diagnosed with poorly differentiated gastric adenocarcinoma on 20 Aug 2020, 22 days after receiving Dose 1. On 20 Aug 2020 (Day 23), the subject visited her physician's office and an upper gastrointestinal endoscopic biopsy revealed infiltrating poorly differentiated adenocarcinoma. No information was available on the symptoms; staging and chemotherapy were planned but no details are available at this time. The subject was withdrawn from the study on 27 Aug 2020 because of the gastric adenocarcinoma that was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the poorly differentiated gastric adenocarcinoma was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	132.18 kg	40.6 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
chronic sinus infection	Chronic sinusitis	1990	Past
Intermittent Headache	Headache	1990	Present
tonsillitis	Tonsillitis	1993	Past
bilateral carpal tunnel syndrome	Carpal tunnel syndrome	2002	Past
bilateral carpal tunnel repair	Carpal tunnel decompression	2003	Past
obesity	Obesity	2004	Present
balloon sinuplasty	Sinuplasty	2011	Past
allergy to cedar	Allergy to plants	2013	Present
allergy to oak	Allergy to plants	2013	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	2013	Present
heartburn	Dyspepsia	2018	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2018	Present
anxiety	Anxiety	NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	12:21

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Atrial fibrillation	Paroxysmal Atrial fibrillation with rapid ventricular response	23AUG2020 (20)		08SEP2020 (36)	00:00	17
2	CARD	Atrial flutter	Atrial Flutter	02SEP2020 (30)	00:00	08SEP2020 (36)	00:00	7
3	VASC	Hypertension	Hypertension	24AUG2020 (21)	00:00	ONGOING		
4	CARD	Left atrial enlargement	Left Atrial Enlargement	09SEP2020 (37)	00:00	ONGOING		
5	CARD	Left ventricular hypertrophy	Left Ventricular Hypertrophy	24AUG2020 (21)	00:00	ONGOING		
6	CARD	Mitral valve incompetence	Mitral Regurgitation	09SEP2020 (37)	00:00	ONGOING		
7	CARD	Mitral valve prolapse	Bileaflet mitral valve prolapse	09SEP2020 (37)	00:00	ONGOING		

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
8	CARD	Myocardial infarction	Prior Septual Myocardinal Infarction	08SEP2020 (36)	00:00	08SEP2020 (36)	00:00	1
9	INJ&P	Skin laceration	Laceration-Left Index Finger	01SEP2020 (29)	00:00	15SEP2020 (43)	00:00	15

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN/P	Y	Resolved (08SEP2020)	NOT RELATED/OTHER: Heart Disease	1	20	Y
2	3	TC/TCN	N	Resolved (08SEP2020)	NOT RELATED/OTHER: Cardiac Disease	1	30	N
3	1	TC	N	Yes	NOT RELATED/OTHER: Medical Illness	1	21	N
4	1	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
5	1	TC	N	Yes	NOT RELATED/OTHER: Medical Illness	1	21	N
6	1	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
7	1	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
8	1	N	N	Resolved (08SEP2020)	NOT RELATED/OTHER: Heart Disease	1	36	N
9	2	TCN	N	Resolved (15SEP2020)	NOT RELATED/OTHER: Hobby Injury	1	29	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Withdrawn	VACCINATION	23AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1083 10831029, a 50-year-old white male with a pertinent medical history of obesity (since 2004), received Dose 1 on 04 Aug 2020. The subject was diagnosed with atrial fibrillation on 23 Aug 2020, 19 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the onset of the atrial fibrillation, hypertension, and left ventricular hypertrophy included naproxen sodium and acetylsalicylic acid (since 1990) for headache; fluticasone propionate (since 2013) for seasonal allergies; omeprazole (since 2018) for gastroesophageal reflux disease; and pregabalin, desvenlafaxine succinate, and lorazepam (all since 2019) for anxiety. On 23 Aug 2020 (Day 20), the subject presented to the emergency room (ER) with palpitations associated with a funny sensation in his head and was hospitalized on 24 Aug 2020 (Day 21). An electrocardiogram (ECG) showed atrial fibrillation with rapid ventricular response of 141 beats/min, no PR interval, normal QRS, and normal-appearing ST and T waves. The ventricular rate was controlled by treatment with diltiazem and a beta blocker. Cardiac telemetry showed a heart rate ranging from 80 to 90's (beats/min). The subject's echocardiography revealed mild left ventricular hypertrophy. The estimated ejection fraction was 55% to 60%. Additional laboratory results showed an elevated blood glucose level of 195 mg/dL (normal range [NR]: 70 - 110 mg/dL). The physician notes stated that a nonfasting glucose test was performed, and the subject had eaten some high-sugar food prior to the ER visit; however, the subject was not treated, nor was the elevated test result reported as an adverse event. An event of elevated glucose was reported in the hospital medical records once. Additional laboratory results included blood urea of 25 mg/dL (NR: 7 - 18 mg/dL) and low blood potassium of 3.4 mmol/L (NR: 3.5 - 5.1 mmol/L).

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Narrative Comment
Additionally, the subject was treated with ketorolac tromethamine 10 mg orally (PO) as needed (PRN) and apixaban 5 mg PO twice a day (BID) (both since 25 Aug 2020) for atrial fibrillation, and metoprolol tartrate 50 mg PO from 25 Aug 2020 to 02 Sep 2020 and then at 50 mg PO BID since 02 Sep 2020 for hypertension. The subject was monitored for his response on the beta blocker and calcium channel blocker. On 25 Aug 2020 (Day 22), the subject's laboratory results showed elevated alanine aminotransferase of 107 IU/L (NR: 30 - 65 IU/L), aspartate aminotransferase of 57 IU/L (NR: 15 - 37 IU/L), chloride of 108 mmol/L (NR: 98 - 107 mmol/L), and magnesium of 2.5 mg/dL (NR: 1.8 - 2.4 mg/dL); and low anion gap of 5 (NR: 7 - 16; units not reported). On the same day (Day 22), the subject was discharged from the hospital and was scheduled for a cardioversion with a transesophageal echocardiogram. On 02 Sep 2020 (Day 30), the subject followed up with his cardiologist for cardio evaluation after hospitalization. On the same day (Day 30), a stress test and cardiac catheterization were performed and the results were not available. An ECG performed that same day was abnormal and showed atrial fibrillation with a nonspecific T-wave abnormality, and the subject was diagnosed with atrial flutter with an onset date of 02 Sep 2020 (Day 30). On 08 Sep 2020 (Day 36), the ECG results revealed new cardiac findings of septal myocardial infarction that was considered probably old per the surgeon's postoperative report, mitral regurgitation, bileaflet mitral valve prolapse, and left atrial enlargement. On the same day (Day 36), the atrial fibrillation and atrial flutter were considered resolved. On 09 Sep 2020 (Day 37), the subject was diagnosed with bileaflet mitral valve prolapse and left atrial enlargement, and mitral regurgitation. On 08 Sep 2020 (Day 36), a transesophageal echocardiography with cardioversion was performed with no complications. The cardiac rhythm was successfully converted from atrial fibrillation to normal sinus rhythm with a ventricular rate of 69 beats per minute. The subject was treated with acetylsalicylic acid 81 mg PO daily (since 30 Sep 2020) as prophylaxis. On 03 Oct 2020 (Day 61), the subject returned to the site for Visit 3 (follow-up safety evaluation). The subject was discontinued from the study intervention on 23 Aug 2020 because of the atrial fibrillation and remains in the study to be evaluated for safety, immunogenicity, and efficacy. The hypertension, mitral valve incompetence, left atrial enlargement, left ventricular hypertrophy, and mitral valve prolapse were ongoing as of the last available report. In the opinion of the investigator, there was no reasonable possibility that the paroxysmal atrial fibrillation with rapid ventricular response was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to medical illness. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	81.91 kg	27.4 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic Rhinitis-Seasonal	Seasonal allergy	1976	Present
Hair Loss	Alopecia	2000	Present
Umbilical hernia	Umbilical hernia	2010	Present
Pectoralis Tendon Tear-Right	Tendon rupture	2013	Past
Pectoralis tendon Tear Repair-Right	Tenoplasty	2013	Past
Partial Achilles Tendon Tear-Right Foot	Tendon rupture	MAR2018	Past
Right Foot Achilles Tendon Repair	Tenoplasty	MAR2018	Past
Stomach Cramps	Abdominal pain upper	03AUG2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06AUG2020 (1)	11:30

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain	Worsening of Abdominal Pain	14AUG2020 (9)	00:00	24AUG2020 (19)	11:32	11	4
2	INFEC	Cellulitis	Phlegmon Formation	20AUG2020 (15)	00:00	20AUG2020 (15)	00:00	1	3
3	GASTR	Diverticular perforation	Ruptured diverticulum	14AUG2020 (9)	00:00	24AUG2020 (19)	00:00	11	4
4	INFEC	Diverticulitis	Diverticulitis	20AUG2020 (15)	00:00	ONGOING			4
5	INJ&P	Postoperative ileus	Post Operative Ileus	18AUG2020 (13)	00:00	23AUG2020 (18)	00:00	6	2
6	GASTR	Small intestinal obstruction	Small Bowel Obstruction	20AUG2020 (15)	00:00	20AUG2020 (15)	00:00	1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (24AUG2020)	NOT RELATED/OTHER: Ruptured Diverticulum	1	9	N
2	TC/TCN	N	Resolved (20AUG2020)	NOT RELATED/OTHER: Diverticulitis	1	15	N
3	TC/TCN/P	Y	Resolved (24AUG2020)	NOT RELATED/OTHER: Infection	1	9	Y
4	TC/TCN	N	Yes	NOT RELATED/OTHER: Infection	1	15	N

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	TC	N	Resolved (23AUG2020)	NOT RELATED/OTHER: Surgical Side Effect	1	13	N
6	TC/TCN	N	Resolved (20AUG2020)	NOT RELATED/OTHER: Ruptured Diverticulum	1	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	06AUG2020	
Withdrawn	VACCINATION	14AUG2020	ADVERSE EVENT
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1083 10831060, a 45-year-old white male with a pertinent medical history of upper abdominal pain (since 03 Aug 2020), received Dose 1 on 06 Aug 2020. The subject was diagnosed with a diverticular perforation on 14 Aug 2020, 8 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the onset of the diverticular perforation included finasteride (since Apr 2020) for hair loss, dicyclomine and omeprazole magnesium (since 11 Aug 2020) for stomach cramps, and acetaminophen (since 11 Aug 2020) for fever. On 06 Aug 2020 (Day 1), the subject did not report any symptoms related to diverticular perforation. On 07 Aug 2020 (Day 2), a magnetic resonance imaging scan with and without contrast showed a benign liver mass. On 08 Aug 2020 (Day 3), the subject had a fever, and on 11 Aug 2020 (Day 6), he experienced abdominal pain and reported both to the site. The subject was prescribed dicyclomine and omeprazole for possible gastritis by his (b) (6), who was a family physician; additionally, the subject was also taking acetaminophen before the onset of the abdominal pain for fever. The subject stated he had abdominal cramps since 03 Aug 2020 (Day -3); however, he did not report this to the clinical research coordinator at the time of screening. On 13 Aug 2020 (Day 8), the subject visited a primary care physician for a Helicobacter pylori test; the result was not provided. On 14 Aug 2020 (Day 9), the subject presented to the emergency department with worsening right-sided abdominal pain and was hospitalized ultimately for a small-bowel obstruction. He was diagnosed with a heterogeneous cecal mass via a computed tomogram of the abdomen/pelvis with contrast performed on the same day. On 16 Aug 2020 (Day 11), 4 benign lymph nodes, ruptured diverticulum, sessile serrated polyps/adenoma, and focal serosal colon adhesions were observed via an exploratory laparotomy. The subject underwent bowel resection with a right hemicolectomy and allograft tissue reinforcement of anastomosis and abdominal wall excision; the right colon and appendix were removed. The pathology was negative for malignancy. On 18 Aug 2020 (Day 13), the subject experienced postoperative ileus. On 20 Aug 2020 (Day 15), the subject was diagnosed with (phlegmon formation), small-intestinal obstruction, and diverticulitis. The small-intestinal obstruction and (phlegmon formation) resolved on the same day (Day 15), and the subject was able to tolerate an oral diet without difficulties. On 23 Aug 2020 (Day 18), the postoperative ileus was considered resolved. On 24 Aug 2020 (Day 19), the subject's laboratory tests showed an elevated alanine aminotransferase of 114 IU/L (normal range [NR]: 16 - 61 IU/L), aspartate aminotransferase of 82 IU/L (NR: 15 - 37 IU/L), immature granulocytes 1.0% (NR: 0% - 0.7%), and repeat immature granulocytes 0.06% (NR: 0% - 0.05%). A culture was performed on an unspecified date, which was negative. The subject recovered from the diverticular perforation and worsening abdominal pain on 24 Aug 2020 (Day 19). The subject was discharged from the hospital on the same day (Day 19) with the following medications: gabapentin 300 mg orally (PO) 3 times a day, docusate sodium 100 mg PO daily, pantoprazole 40 mg PO every morning, sucralfate 1 g PO 4 times a day as needed, and tramadol 50 mg PO every 8 hours. The investigator considered the diverticular perforation as life-threatening. On 18 Sep 2020 (Day 44), the subject reported he was not stable enough to travel or attend the safety visit. The subject was discontinued from the study intervention on 14 Aug 2020 because of the diverticular perforation and remains in the study to be evaluated for safety, immunogenicity, and efficacy. The diverticulitis was ongoing as of the last available report. In the opinion of the investigator, there was no reasonable possibility that the diverticular perforation was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to infection. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	73.75 kg	23.3 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
INSOMNIA	Insomnia	1990	Present
GERD	Gastrooesophageal reflux disease	2010	Present
Alcoholic Cirrhosis	Cirrhosis alcoholic	2019	Present
Esophageal Ulcers	Oesophageal ulcer	2019	Present
Esophageal varices	Varices oesophageal	2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	14:43

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Blood loss anaemia	Acute blood loss anemia	07SEP2020 (20)		09SEP2020 (22)		3	3
2	HEPAT	Cirrhosis alcoholic	Worsening of alcoholic cirrhosis	07SEP2020 (20)		ONGOING			3
3	GASTR	Gastrointestinal haemorrhage	GI Bleed	07SEP2020 (20)		09SEP2020 (22)		3	3
4	GASTR	Haematochezia	Hematochezia	07SEP2020 (20)		09SEP2020 (22)		3	3
5	METAB	Hypernatraemia	Hypernatremia	07SEP2020 (20)		09SEP2020 (22)		3	2
6	GASTR	Oesophageal ulcer	Worsening of esophageal ulcers	07SEP2020 (20)		09SEP2020 (22)		3	3
7	BLOOD	Thrombocytopenia	Thrombocytopenia	07SEP2020 (20)		ONGOING			3
8	GASTR	Varices oesophageal	Worsening of esophageal varices	07SEP2020 (20)		09SEP2020 (22)		3	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (09SEP2020)	NOT RELATED/OTHER: due to varices	1	20	N
2	N	N	Yes	NOT RELATED/OTHER: Worsening of previous condition	1	20	N
3	TC/TCN/P/W	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: Due to Ulcers	1	20	Y
4	TC	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Due to ulcers	1	20	N
5	N	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Spontaneous event	1	20	N

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
6	TC/TCN	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Worsening of previous condition	1	20	N
7	N	N	Yes	NOT RELATED/OTHER: Due to cirrhosis	1	20	N
8	TC/TCN	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Worsening of previous condition	1	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	09SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	09SEP2020	ADVERSE EVENT

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Narrative Comment
Subject C4591001 1087 10871121, a 67-year-old white male, with a pertinent medical history of gastroesophageal reflux disease (since 2010) and alcoholic cirrhosis, esophageal ulcers, and esophageal varices (all since 2019), received Dose 1 on 19 Aug 2020. The subject was diagnosed with a gastrointestinal hemorrhage on 07 Sep 2020, 19 days after receiving Dose 1. Concomitant medication reported within 2 weeks before the onset of the event included tramadol (since 01 Jun 2020) for insomnia. On 07 Sep 2020 (Day 20), the subject was diagnosed with anemia due to blood loss, alcoholic cirrhosis, hematochezia, esophageal ulcer, thrombocytopenia, esophageal varices, and hypernatremia. An esophagogastroduodenoscopy performed the next day revealed postbanding ulcers and residual esophageal varices. The esophageal varices were rebanded, and the subject was observed overnight. It was reported that the subject failed to report a past history of esophageal varices and alcoholic cirrhosis. Laboratory results on 08 Sep 2020 (Day 21) revealed a hematocrit (Hct) of 22.9, hemoglobin (Hb) of 7.1, and platelet count of 70. On 09 Sep 2020 (Day 22), laboratory results showed Hct of 21.4, Hb of 7.0, sodium of 143, potassium of 3.6, chloride of 115, carbon dioxide (CO2) of 21.0, blood urea nitrogen (BUN) of 14, and creatinine of 0.73 (normal ranges and units were not reported). The clinical chemistry laboratory results on 07 Sep 2020 (Day 20) showed sodium of 147, potassium of 3.7, chloride of 116, CO2 of 16.6, BUN of 22, creatinine of 1.07, international normalized ratio (INR) of 1.18, albumin of 3.0, total protein of 6.5, direct bilirubin of 0.61, alanine aminotransferase (ALT) of 24, aspartate aminotransferase (AST) of 28, and alkaline phosphatase (ALP) of 96 (normal ranges and units were not reported). Repeat laboratory results on 08 Sep 2020 (Day 21) showed a white blood cell count of 2.9, sodium of 147, potassium of 3.7, chloride of 119, CO2 of 19.8, BUN of 18, creatinine of 0.86, albumin of 2.7, total protein of 5.3, ALT of 15, AST of 31, and ALP of 82 (normal ranges and units were not reported). The anemia, gastrointestinal hemorrhage, hematochezia, hypernatremia, esophageal ulcer, and esophageal varices were considered resolved on 09 Sep 2020 (Day 22). It was noted that the bleeding did not reoccur, and the subject was discharged on the same day (Day 22). The subject notified the site that he was feeling well and had recovered from the event. The subject was withdrawn from the study on 09 Sep 2020 because of the gastrointestinal hemorrhage. The alcoholic cirrhosis and thrombocytopenia were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the gastrointestinal hemorrhage was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to ulcers. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.9 cm	92.5 kg	27.7 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	2005	Present
GROUT	Gout	2017	Present
BILATERAL FOOT PAIN	Pain in extremity	2018	Present
BENIGN PROSTATIC HYPERPLASIA	Benign prostatic hyperplasia	JAN2020	Present
CONGESTIVE HEART FAILURE	Cardiac failure congestive	FEB2020	Present
CHRONIC KIDNEY DISEASE	Chronic kidney disease	FEB2020	Present
CORONARY ARTERY DISEASE	Coronary artery disease	FEB2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	13:02

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	VASC	Accelerated hypertension	Accelerated Hypertension	03SEP2020 (9)		06SEP2020 (12)		4	3	N	N
2	RENAL	Acute kidney injury	Acute Kidney Injury	03SEP2020 (9)		07SEP2020 (13)		5	2	N	N
3	RESP	Acute respiratory failure	Acute Respiratory Failure	03SEP2020 (9)		04SEP2020 (10)		2	3	TC	N
4	CARD	Atrial fibrillation	PAROXYSMAL ATRIAL Fibrillation	03SEP2020 (9)		08SEP2020 (14)		6	2	N	N
5	CARD	Cardiac failure congestive	Worsening of Chronic Congestive Heart Failure	03SEP2020 (9)		08SEP2020 (14)		6	3	TC/P/W	Y
6	METAB	Dehydration	DEHYDRATION	03SEP2020 (9)		04SEP2020 (10)		2	2	TCN	N
7	NERV	Dizziness	Dizziness	05SEP2020 (11)		08SEP2020 (14)		4	2	TCN	N
8	RESP	Dyspnoea	SHORTNESS OF BREATH	03SEP2020 (9)		04SEP2020 (10)		2	3	N	N
9	METAB	Hypokalaemia	HYPOKALEMIA	04SEP2020 (10)		06SEP2020 (12)		3	2	TC	N
10	VASC	Hypotension	Hypotension	05SEP2020 (11)		07SEP2020 (13)		3	2	N	N
11	MUSC	Pain in extremity	WORSENING OF BILATERAL FOOT PAIN	05SEP2020 (11)		06SEP2020 (12)		2	2	TC	N
12	RESP	Pulmonary oedema	BILATERAL PULMONARY EDEMA	03SEP2020 (9)		05SEP2020 (11)		3	2	N	N

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
13	GENRL	Pyrexia	LOW-GRADE FEVER	05SEP2020 (11)		06SEP2020 (12)		2	2	N	N
14	INFEC	Urinary tract infection	Urinary Tract Infection	03SEP2020 (9)		08SEP2020 (14)	08:08	6	2	TC	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (06SEP2020)	NOT RELATED/OTHER: worsening of pre-existing condition	1	9	N
2	Resolved (07SEP2020)	NOT RELATED/OTHER: Dehydration	1	9	N
3	Resolved (04SEP2020)	NOT RELATED/OTHER: due to congestive heart failure	1	9	N
4	Resolved (08SEP2020)	NOT RELATED/OTHER: URINARY TRACT INFECTION	1	9	N
5	Resolved (08SEP2020)	NOT RELATED/OTHER: worsening of pre-existing condition	1	9	Y
6	Resolved (04SEP2020)	NOT RELATED/OTHER: DUE TO DIURETICS	1	9	N
7	Resolved (08SEP2020)	NOT RELATED/OTHER: due to UTI	1	11	N
8	Resolved (04SEP2020)	NOT RELATED/OTHER: CONGESTIVE HEART FAILURE	1	9	N
9	Resolved (06SEP2020)	NOT RELATED/OTHER: DUE TO DIURESIS	1	10	N
10	Resolved (07SEP2020)	NOT RELATED/OTHER: due to diuresis	1	11	N

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Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
11	Resolved (06SEP2020)	NOT RELATED/OTHER: WORSENING OF PRE-EXISTING CONDITION	1	11	N
12	Resolved (05SEP2020)	NOT RELATED/OTHER: CONGESTIVE HEART FAILURE	1	9	N
13	Resolved (06SEP2020)	NOT RELATED/OTHER: URINARY TRACT INFECTION	1	11	N
14	Resolved (08SEP2020)	NOT RELATED/OTHER: spontaneous	1	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	16SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	16SEP2020	ADVERSE EVENT

Narrative Comment

Subject C4591001 1087 10871228, a 72-year-old white male with a pertinent medical history of hypertension (since 2005), benign prostatic hyperplasia (since Jan 2020), and congestive cardiac failure, chronic kidney disease and coronary artery disease (all since Feb 2020), received Dose 1 on 26 Aug 2020. The subject experienced worsening of chronic congestive heart failure on 03 Sep 2020, 8 days after receiving Dose 1.

Concomitant medications reported within 2 weeks prior to the onset of worsening of chronic congestive heart failure included metoprolol (from 2005 to 03 Sep 2020) for hypertension, rivaroxaban (since Feb 2020) for coronary artery disease, colchicine (since Feb 2020) for gout, tamsulosin (since Mar 2020) for benign prostatic hyperplasia, and nifedipine (since Jul 2020) for hypertension.

On 03 Sep 2020 (Day 9), the subject went to emergency room with dyspnea (shortness of breath), worsening hypertension, and acute kidney injury and was subsequently admitted with exacerbation of chronic congestive heart failure resulting in acute respiratory failure. A chest x-ray performed on the same day (Day 9), revealed bilateral pulmonary edema for which the subject was treated with furosemide intravenously, then transitioned to oral (PO). While in the hospital, the subject's SARS-CoV-2 (COVID-19) test was negative. The subject also experienced urinary tract infection, paroxysmal atrial fibrillation, and dehydration (all on 03 Sep 2020 [Day 9]); hypokalemia on 04 Sep 2020 (Day 10); and dizziness, hypotension, worsening of bilateral foot pain, and pyrexia (low-grade fever) (all on 05 Sep 2020 [Day 11]). On 04 Sep 2020 (Day 10), the dyspnea, acute respiratory failure, and dehydration resolved and on 05 Sep 2020 (Day 11), the pulmonary edema resolved. On 06 Sep 2020 (Day 12), the worsening hypertension, hypokalemia, worsening of bilateral foot pain, and pyrexia resolved. On 07 Sep 2020 (Day 13), the acute kidney injury and hypotension resolved. On 08 Sep 2020 (Day 14), the atrial fibrillation, worsening of chronic congestive heart failure, dizziness, and urinary tract infection resolved, and the subject was discharged on furosemide PO and supplemental oxygen.

The subject was withdrawn from the study on 16 Sep 2020 because of the worsening of chronic congestive heart failure.

In the opinion of the investigator, there was no reasonable possibility that the worsening of chronic congestive heart failure was related to the study intervention, concomitant medications, or clinical trial procedures; but rather it was related to worsening of a pre-existing condition. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	Asian	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	55.92 kg	23.3 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to under cooked shrimp	Food allergy	2005	Present
POLYCYSTIC OVARIAN SYNDROME	Polycystic ovaries	2005	Present
Vitamin D Deficiency	Vitamin D deficiency	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14OCT2020 (1)	13:08

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	24OCT2020 (11)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1				P	N	Yes	Study Treatment	1	11	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14OCT2020	
Withdrawn	VACCINATION	05NOV2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1087 10871557, a 34-year-old Asian female with a pertinent medical history of polycystic ovaries (since 2005), received Dose 1 on 14 Oct 2020. The subject had a positive urine pregnancy test on 05 Nov 2020 (Day 23) with an estimated date of conception of 24 Oct 2020, 10 days after receiving Dose 1. Concomitant medications reported 2 weeks prior to the exposure during pregnancy included cyanocobalamin (since 2018) as a dietary supplement and cholecalciferol (since 2018) for vitamin deficiency. A repeat pregnancy test was also positive. The subject confirmed she used contraceptives (condom with spermicide), was unaware that she was pregnant, and planned to follow-up with her obstetrician/gynecologist. The first date of her last menstrual period was 17 Sep 2020 and the estimated date of conception was 24 Oct 2020 (Day 11). The subject had no previous pregnancies. She did not smoke, drink alcohol, or use illicit drugs during her pregnancy. She also reported that her 34-year-old husband did not have any potential environmental or occupational exposures. The subject and her husband did not have any family history of congenital abnormalities, genetic diseases, or consanguinity. Her husband smoked, drank alcohol, and used recreational drugs during her pregnancy. The subject was discontinued from the study intervention on 05 Nov 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the exposure during pregnancy was related to the study intervention, concomitant medications, or clinical trial procedures.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
150 cm	57.6 kg	25.6 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Insect Allergy	Allergy to arthropod sting	1973	Present
Mushroom Allergy	Food allergy	1973	Present
Allergic Rhinitis	Rhinitis allergic	1973	Present
Allergy to Pollen	Seasonal allergy	1973	Present
Grass Allergy	Seasonal allergy	1973	Present
Osteopenia	Osteopenia	1996	Present
Chronic Back Pain	Back pain	2000	Present
Post-Menopausal	Postmenopause	2000	Present
Chronic Urinary Tract Infections	Urinary tract infection	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vaginal Dryness	Vulvovaginal dryness	2000	Present
Insomnia	Insomnia	2015	Present
Osteoarthritis of Neck	Spinal osteoarthritis	2015	Present
Recurrent GERD	Gastrooesophageal reflux disease	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17SEP2020 (1)	13:08

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Headache	Headache	30SEP2020 (14)		20OCT2020 (34)		21	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/P	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Possible sinus infection	1	14	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu vaccine	INFLUENZA VACCINE	03OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
Withdrawn	VACCINATION	13NOV2020	ADVERSE EVENT
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1090 10901415, a 68-year-old white female with a pertinent medical history of allergic rhinitis (since 1973), received Dose 1 on 17 Sep 2020. The subject reported headache on 30 Sep 2020, 13 days after receiving Dose 1. The headache resolved on 20 Oct 2020 (Day 34). The subject was discontinued from the study intervention on 13 Nov 2020 because of the headache and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the headache was related to the study intervention, but rather it was related to possible sinus infection.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.6 cm	80.6 kg	29.7 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	2007	Present
Recurrent Constipation	Constipation	2007	Present
Depression	Depression	2007	Present
Irritable Bowel Syndrome	Irritable bowel syndrome	2007	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	11:18

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Urticaria	Hives, upper chest	19OCT2020 (4)		22OCT2020 (7)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	2	TC/P	N	Resolved (22OCT2020)	Study Treatment	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
Withdrawn	VACCINATION	04NOV2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1090 10901507, a 31-year-old black or African American female with no pertinent medical history, received Dose 1 on 16 Oct 2020. The subject experienced urticaria (hives, upper chest) on 19 Oct 2020, 3 days after receiving Dose 1. On 22 Oct 2020 (Day 7), the urticaria resolved. The subject was discontinued from the study intervention on 04 Nov 2020 because of the urticaria and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the urticaria was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.29 cm	61.91 kg	23.7 kg/m2	25AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	17:21

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	28AUG2020 (4)	00:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: PREGNANCY	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Withdrawn	VACCINATION	18SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1093 10931058, a 25-year-old white female with no reported medical history, received Dose 1 on 25 Aug 2020. The subject reported an exposure during pregnancy on 28 Aug 2020, 3 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the pregnancy confirmation included ethinyl estradiol/levonorgestrel (since 01 Jun 2020) for contraception. On 18 Sep 2020 (Day 25), the subject came in for her second vaccination visit and a urine pregnancy test result was positive; therefore, the second dose was not administered. The subject was using birth control during this time. The first day of her last menstrual period was reported as 27 Jul 2020 (Day -29). She did not have any medical risk factors or a previous pregnancy. The exposure during pregnancy was considered an important medical event by the investigator. The estimated date of conception or delivery was not reported at the time of this report. The subject was discontinued from the study intervention on 18 Sep 2020 because of exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the exposure during pregnancy was related to the study intervention, concomitant medications, or clinical trial procedures.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	99.7 kg	35.3 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type II Diabetes	Type 2 diabetes mellitus	2000	Present
Hypercholesterolemia	Hypercholesterolaemia	2014	Present
Excessive Perspiration	Hyperhidrosis	2014	Present
Hypertension	Hypertension	2014	Present
Deep Vein Thrombosis	Deep vein thrombosis	2015	Present
Itching of Legs	Pruritus	2015	Present
Osteomyelitis	Osteomyelitis	2017	Past
Post Traumatic Stress Disorder	Post-traumatic stress disorder	2017	Present
Amputation of 10 Toes	Toe amputation	2017	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Environmental Allergies	Hypersensitivity	2019	Present
Pain in feet post-op toe amputations	Procedural pain	DEC2019	Present
Cataracts Left eye	Cataract	JUN2020	Past
cataracts right eye	Cataract	JUN2020	Past
Peripheral Neuropathy secondary to Type II Diabetes	Diabetic neuropathy	05JUN2020	Present
Right Eye Cataract Surgery	Cataract operation	12AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	12:35

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Diabetic foot	Diabetic Foot Ulcer R Foot	14SEP2020 (20)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TCN/W	N	Yes	NOT RELATED/OTHER: Diabetes	1	20	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	16SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	16SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1095 10951141, a 50-year-old white female with a pertinent medical history of type 2 diabetes mellitus (since 2000), toe amputation (in 2017), and diabetic neuropathy (since 05 Jun 2020), received Dose 1 on 26 Aug 2020. The subject was diagnosed with a diabetic foot ulcer (right foot) on 14 Sep 2020, 19 days after receiving Dose 1. The subject was withdrawn from the study on 16 Sep 2020 due to diabetic foot. The diabetic foot ulcer (right foot) was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the diabetic foot ulcer was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	87.5 kg	31.4 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	2006	Present
vasectomy	Vasectomy	2014	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29AUG2020 (1)	15:16

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Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1			Coronary Artery Disease	05SEP2020 (8)		ONGOING			2
2	CARD	Acute myocardial infarction	STEMI: ST elevation Myocardial Infarction	05SEP2020 (8)		09SEP2020 (12)		5	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: CAD	1	8	N
2	TC/TCN/P	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: undiagnosed Obstructive CAD	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine 1 dose IM once for influenza prevention	INFLUENZA VACCINE	28OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29AUG2020	
Withdrawn	VACCINATION	05SEP2020	ADVERSE EVENT
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1095 10951173, a 49-year-old Asian male with no pertinent medical history, received Dose 1 on 29 Aug 2020. The subject experienced an acute myocardial infarction on 05 Sep 2020, 7 days after receiving Dose 1. Concomitant medication reported 2 weeks prior to the acute myocardial infarction included loratadine (since 2018) for seasonal allergies. On 05 Sep 2020 (Day 8), the site received a phone call from the subject reporting that he had a heart attack in the morning. The subject reported that he experienced nausea and chest tightness upon waking up that day requiring an emergency room (ER) visit. A COVID-19 test performed in the ER was negative. He was transferred to a local hospital; a subsequent angiogram performed on 05 Sep 2020 (Day 8) revealed right-sided coronary blockage resulting in a myocardial infarction. There was no evidence of pulmonary embolic disease, acute cardiopulmonary abnormality, or aortic dissection. The subject reported that 4 stents were placed. Blood culture for bacteriology on 06 Sep 2020 (Day 9) was negative. The acute myocardial infarction was considered resolved on 09 Sep 2020 (Day 12) and the subject was discharged from the hospital. The discharge medications included atorvastatin 80 mg once daily (QD), prasugrel hydrochloride 10 mg orally (PO) QD, metoprolol 25 mg PO QD, and acetylsalicylic acid 81 mg PO QD for acute myocardial infarction. The subject was discontinued from the study intervention on 05 Sep 2020 because of the acute myocardial infarction and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the acute myocardial infarction was related to the study intervention, but rather it was related to undiagnosed obstructive coronary artery disease. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
153.67 cm	87.64 kg	37 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CAT ALLERGY	Allergy to animal	2000	Present
ATHLETIC ASTHMA	Asthma exercise induced	2004	Past
INTERMITTENT HEADACHES	Headache	2005	Present
MASTITIS	Mastitis	2016	Past
CESAREAN SECTION	Caesarean section	08JUN2016	Past
MASTITIS REMOVAL SURGERY	Breast operation	OCT2016	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	18:11

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	14AUG2020 (1)		22SEP2020 (40)		40
2	RESP	Nasal congestion	Nasal congestion	05OCT2020 (53)		ONGOING		
3	RESP	Oropharyngeal pain	Sore throat	05OCT2020 (53)		07OCT2020 (55)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		P	N	Resolved (22SEP2020)	NOT RELATED/OTHER: PREGNANCY	1	1	Y
2	1	N	N	Yes	NOT RELATED/OTHER: Personal illness	1	53	N
3	1	N	N	Resolved (07OCT2020)	NOT RELATED/OTHER: Personal illness	1	53	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Withdrawn	VACCINATION	04SEP2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1096 10961031, a 22-year-old white female with a pertinent obstetrical history of 2 previous pregnancies, 1 full term pregnancy with live birth on requiring a caesarean section (on 08 Jun 2016) and a miscarriage at 13 weeks (in Oct 2019) with a history of an irregular menstrual cycle (since Oct 2019), received Dose 1 on 14 Aug 2020. The subject reported an exposure during pregnancy on 14 Aug 2020, on the day of Dose 1. On 14 Aug 2020 (Day 1), the subject's pregnancy test at Visit 1 was negative prior to receiving Dose 1. On 04 Sep 2020 (Day 22), during Visit 2 prior to Dose 2, the subject's urine pregnancy test was positive. A repeat pregnancy test was also positive. The subject's first day of her last menstrual period was 04 Jul 2020 and the estimated date of conception was 09 Aug 2020. Gestation at the time of initial exposure was first trimester. An ultrasound on 21 Sep 2020 (Day 39) confirmed the pregnancy with a gestational age of 6 weeks and 2 days with no abnormalities. It was reported that the mother did not smoke, drink alcohol, or use illicit drugs. .On 22 Sep 2020 (Day 40), the subject underwent an elective abortion at 6 weeks and 3 days of gestation. The subject was discontinued from the study intervention on 04 Sep 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the exposure during pregnancy was related to the study intervention, concomitant medications or clinical trial procedures.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	66.82 kg	26.9 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
POSTMENOPAUSAL	Postmenopause	1999	Present
ASTHMA	Asthma	2012	Present
HYSTERECTOMY	Hysterectomy	2014	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11SEP2020 (1)	15:37

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain upper	ABDOMINAL PAIN RUQ	SEP2020 ()		30SEP2020 (20)			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	P	N	Resolved (30SEP2020)	NOT RELATED/OTHER: GALBLADDER DESEASE			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Withdrawn	VACCINATION	30SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1109 11091503, a 64-year-old white female with no pertinent medical history, received Dose 1 on 11 Sep 2020. The subject experienced abdominal pain upper (right quadrant) on an unspecified date in Sep 2020. On 30 Sep 2020 (Day 20), the abdominal pain upper resolved. The subject was discontinued from the study intervention on 30 Sep 2020 because of the abdominal pain upper and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the abdominal pain upper was related to the study intervention, but rather it was related to gallbladder disease.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	77.36 kg	26.7 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Partial Hysterectomy	Hysterectomy	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	14:39

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Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	SKIN	Pruritus	Generalized Pruritus	12AUG2020 (2)		12AUG2020 (2)	
2	CARD	Tachycardia	Tachycardia	12AUG2020 (2)		12AUG2020 (2)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	3	TC	N	Resolved (12AUG2020)	Study Treatment	1	2	N
2	1	3	TC/P	N	Resolved (12AUG2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Withdrawn	VACCINATION	12AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1112 11121118, a 56-year-old white female with no pertinent medical history, received Dose 1 on 11 Aug 2020. The subject reported pruritus and tachycardia on 12 Aug 2020 (resolved the same day), 1 day after receiving Dose 1. The subject was discontinued from the study intervention on 12 Aug 2020 because of the pruritus and tachycardia and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the pruritus and tachycardia were related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	52 kg	21.6 kg/m2	06OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	1970	Present
Hysterectomy	Hysterectomy	1984	Past
Ovarian Cysts	Ovarian cyst	1984	Past
Postmenopausal	Postmenopause	1995	Present
Anxiety	Anxiety	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06OCT2020 (1)	10:38

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	Chills	06OCT2020 (1)		07OCT2020 (2)	
2	NERV	Headache	Headaches	06OCT2020 (1)		07OCT2020 (2)	
3	MUSC	Myalgia	Muscle Aches	06OCT2020 (1)		07OCT2020 (2)	
4	GENRL	Pyrexia	Fever	06OCT2020 (1)		07OCT2020 (2)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	TC/P	N	Resolved (07OCT2020)	Study Treatment	1	1	Y
2	2	3	TC/P	N	Resolved (07OCT2020)	Study Treatment	1	1	Y
3	2	2	TC	N	Resolved (07OCT2020)	Study Treatment	1	1	N
4	2	2	TC/P	N	Resolved (07OCT2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06OCT2020	
Withdrawn	VACCINATION	07OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1112 11121255, a 65-year-old white female with no pertinent medical history, received Dose 1 on 06 Oct 2020. The subject experienced chills, headache, and pyrexia on 06 Oct 2020 after Dose 1 administration. On the same day (Day 1), the subject also experienced myalgia. The chills, headache, pyrexia, and myalgia resolved on 07 Oct 2020 (Day 2). The subject was discontinued from the study intervention on 07 Oct 2020 because of the chills, headache, and pyrexia and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the chills, headache, and pyrexia were related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	79	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	77.27 kg	27.4 kg/m2	21OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergic rhinitis	Seasonal allergy	1947	Present
Perennial allergic rhinitis	Rhinitis perennial	1955	Present
Endometriosis	Endometriosis	1972	Past
Hysterectomy	Hysterectomy	1974	Past
Irritable Bowel Syndrome	Irritable bowel syndrome	1980	Present
Osteoarthritis, generalized	Osteoarthritis	1990	Present
Hypertension	Hypertension	1995	Present
Meralgia Paresthetica, right thigh	Meralgia paraesthetica	2005	Present
Hyperlipidemia	Hyperlipidaemia	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Esophageal stricture	Oesophageal stenosis	2010	Present
Diverticulitis	Diverticulitis	2013	Present
Osteopenia	Osteopenia	2013	Present
Asthma, moderate	Asthma	2015	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2015	Present
Diabetes, type 2	Type 2 diabetes mellitus	2015	Present
Depression, situational	Adjustment disorder with depressed mood	APR2017	Present
Vaginal dryness	Vulvovaginal dryness	SEP2017	Present
Fracture, left foot	Foot fracture	20JAN2020	Past
Surgery, left foot	Foot operation	20JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21OCT2020 (1)	17:28

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Diarrhoea	Diarrhea	22OCT2020 (2)		25OCT2020 (5)	
2	GENRL	Fatigue	Fatigue	22OCT2020 (2)		28OCT2020 (8)	
3	NERV	Headache	Headache	22OCT2020 (2)		28OCT2020 (8)	

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
4	MUSC	Myalgia	Muscle Aches	22OCT2020 (2)		28OCT2020 (8)	
5	GASTR	Nausea	Nausea	22OCT2020 (2)		25OCT2020 (5)	
6	GASTR	Vomiting	Vomiting	25OCT2020 (5)		25OCT2020 (5)	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	3	TC/W	N	Resolved (25OCT2020)	Study Treatment	1	2	Y
2	7	2	P	N	Resolved (28OCT2020)	Study Treatment	1	2	Y
3	7	2	TC	N	Resolved (28OCT2020)	Study Treatment	1	2	N
4	7	2	TC	N	Resolved (28OCT2020)	Study Treatment	1	2	N
5	4	2	TC	N	Resolved (25OCT2020)	Study Treatment	1	2	N
6	1	2	N	N	Resolved (25OCT2020)	Study Treatment	1	5	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21OCT2020	
Withdrawn	VACCINATION	26OCT2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	26OCT2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1112 11121337, a 79-year-old white female with a pertinent medical history of irritable bowel syndrome (since 1980), diverticulitis (since 2013), and type 2 diabetes mellitus (since 2015), received Dose 1 on 21 Oct 2020. The subject experienced diarrhea and fatigue on 22 Oct 2020, 1 day after receiving Dose 1. On 22 Oct 2020 (Day 2), the subject also experienced headache, myalgia, and nausea. On 25 Oct 2020 (Day 5), the subject had vomiting. The diarrhea, nausea, and vomiting resolved on the same day (Day 5). The subject was discontinued from the study intervention on 26 Oct 2020 because of the fatigue and was later withdrawn from the study on the same day because of the diarrhea. The fatigue, headache, and myalgia resolved on 28 Oct 2020 (Day 8). In the opinion of the investigator, there was a reasonable possibility that the diarrhea and fatigue were related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	60 kg	21.3 kg/m2	06OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
VISION IMPAIRMENT, BILATERAL	Visual impairment	1990	Present
ALLERGY, NICKEL	Allergy to metals	1995	Present
DEPRESSION	Depression	2016	Present
ANXIETY	Anxiety	2019	Present
CANNABIS HYPEREMESIS SYNDROME	Cannabinoid hyperemesis syndrome	2019	Present
CANNABIS ABUSE	Drug abuse	2019	Present
VENOUS THROMBOSIS/EMBOLISM	Embolism venous	2019	Present
INSOMNIA	Insomnia	2019	Present
MIGRAINE	Migraine	2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BUTALBITAL USE DISORDER	Drug abuse	15MAR2019	Present
SUICIDAL IDEATION W/ ATTEMPT	Suicide attempt	15MAR2019	Past
MEDICATION TREATEMENT NONCOMPLAINCE	Treatment noncompliance	15MAR2019	Present
SUICIDAL IDEATION W/ ATTEMPT	Suicide attempt	24DEC2019	Past
EPIGASTRIC PAIN W/ ADMISSION	Abdominal pain upper	24SEP2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06OCT2020 (1)	14:05

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain	ABDOMINAL PAIN	26OCT2020 (21)		27OCT2020 (22)		2	2
2	PSYCH	Depression	DEPRESSION, WORSENING	19OCT2020 (14)		ONGOING			3
3	GASTR	Gastritis	ACUTE GASTRITIS W/O HEMMORRHAGE	23OCT2020 (18)		ONGOING			2
4	PSYCH	Suicide attempt	SUICIDAL IDEATION WITH ATTEMPT	19OCT2020 (14)		26OCT2020 (21)		8	3
5	GASTR	Vomiting	BILIOUS VOMITING	23OCT2020 (18)		27OCT2020 (22)	01:26	5	3

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Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (27OCT2020)	NOT RELATED/OTHER: ACUTE GASTRITIS	1	21	N
2	TCN	N	Yes	NOT RELATED/OTHER: SITUATIONAL	1	14	N
3	TC/TCN	N	Yes	NOT RELATED/OTHER: UNKNOWN ETIOLOGY	1	18	N
4	TC/TCN/W	Y	Resolved (26OCT2020)	NOT RELATED/OTHER: MAJOR DEPRESSION	1	14	Y
5	TC/TCN	N	Resolved (27OCT2020)	NOT RELATED/OTHER: ACTUE GASTRITIS	1	18	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	06OCT2020	

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	26OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1117 11171186, a 30-year-old black or African American female with a pertinent medical history of depression (since 2016), anxiety and insomnia (both since 2019), drug abuse (cannabis abuse and butalbital use disorder; both since 15 Mar 2019), treatment noncompliance (since 15 Mar 2019), and suicide attempt (on 15 Mar 2019 and 24 Dec 2019), received Dose 1 on 06 Oct 2020. The subject attempted suicide on 19 Oct 2020, 13 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the suicide attempt included aspirin/butalbital/caffeine for migraine, lorazepam for anxiety, ondansetron for nausea/vomiting, mirtazapine (7.5 mg from Jun 2020 and 30 mg from an unspecified date), celecoxib, loperamide hydrochloride, omeprazole, sertraline hydrochloride, and topiramate for unspecified indications, and trazodone for sleep (all from unknown dates). On 19 Oct 2020 (Day 14), the subject experienced worsening of depression and presented to the emergency department (ED) via emergency medical services. The subject reported suicidal ideation and attempted to end her life due to depression related to family issues and stress a few days prior to this report. Her plan was to (b) (6) The subject was hospitalized for depression with suicidal ideation and treated with haloperidol 5 mg, lorazepam 2 mg, and trazodone 100 mg (all on 19 Oct 2020), hydroxyzine 25 mg (on 19 Oct 2020 and 20 Oct 2020), sertraline 100 mg (on 20 Oct 2020), and fluoxetine 10 mg (since 21 Oct 2020). On 23 Oct 2020 (Day 18), the subject developed acute gastritis without hemorrhage and bilious vomiting with nausea. On 26 Oct 2020 (Day 21), the subject denied suicidal ideation and self-harm thoughts. On that same day (Day 21), the suicide attempt was considered resolved and the subject was discharged from the hospital. Of note, the subject had a prior history of psychiatric admission (in Dec 2019) for similar behavior and had previously struggled with anxiety for the past 2 years requiring hospitalization. The subject did not disclose the prior history of depression including prior suicide attempts, treatment noncompliance, drug abuse (cannabis abuse and butalbital/aspirin/caffeine use disorder), anxiety, insomnia, at the time of screening. On 26 Oct 2020 (Day 21), the subject was re-admitted to the ED as she experienced abdominal pain (epigastric pain) with a diagnosis of acute gastritis without hemorrhage and bilious vomiting with nausea. The subject refused advised treatments and requested pain medication and benzodiazepines for which the request for pain medication and benzodiazepines was refused by the ED. The subject was treated medically with diphenhydramine 25 mg, famotidine 20 mg, hydroxyzine 25 mg, ioversol at 350/100 mL, aluminum/magnesium/simethicone/lidocaine 40 mL, metoclopramide 10 mg, morphine 1 mg, and ondansetron 4 mg (all on 26 Oct 2020). The abdominal pain and bilious vomiting resolved on 27 Oct 2020 (Day 22). The subject was discharged from the ED on 27 Oct 2020 (Day 22) with the following medications: aripiprazole 2 mg, famotidine 20 mg, and fluoxetine 10 mg; all starting from 27 Oct 2020. The subject was discontinued from the study intervention on 26 Oct 2020 since she no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy. The worsening depression and acute gastritis without hemorrhage were ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the suicide attempt was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a major depression. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	74	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
189 cm	130.4 kg	36.5 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	1990	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1990	Present
hyperlipidemia	Hyperlipidaemia	2005	Present
Allergy to Allbuterol	Drug hypersensitivity	2020	Present
Post Traumatic stress disorder	Post-traumatic stress disorder	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	13:18

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Diarrhoea	Diarrhea	12AUG2020 (2)		14AUG2020 (4)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	3	TC/P/W	N	Resolved (14AUG2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Withdrawn	VACCINATION	14AUG2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	14AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1120 11201127, a 74-year-old white male with no pertinent medical history, received Dose 1 on 11 Aug 2020. The subject experienced diarrhea on 12 Aug 2020, 1 day after receiving Dose 1. The subject was withdrawn from the study on 14 Aug 2020 because of the diarrhea, which resolved on the same day (Day 4). In the opinion of the investigator, there was a reasonable possibility that the diarrhea was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178 cm	88.4 kg	27.9 kg/m2	28OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergy to bee stings	Allergy to arthropod sting	1965	Present
depression	Depression	1980	Present
vasectomy	Vasectomy	1989	Past
nephrogenic diabetes insipidus	Nephrogenic diabetes insipidus	2000	Present
hyperlipidemia	Hyperlipidaemia	2017	Present
pacemaker	Cardiac pacemaker insertion	APR2019	Present
anemia	Anaemia	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28OCT2020 (1)	14:30

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Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	PSYCH	Depression	worsening of depression	29OCT2020 (2)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	P	N	Yes	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28OCT2020	
Withdrawn	VACCINATION	29OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1120 11201408, a 71-year-old white male with a pertinent medical history of depression (since 1980), received Dose 1 on 28 Oct 2020. The subject experienced worsening of depression on 29 Oct 2020, 1 day after receiving Dose 1. The subject was discontinued from the study intervention on 29 Oct 2020 because of worsening of the depression that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the worsening of the depression was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	24	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline
No Vital Signs - Baseline

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Presyncope	pre-syncope	11SEP2020 (1)		11SEP2020 (1)		1
2	GASTR	Vomiting	vomiting	11SEP2020 (1)		11SEP2020 (1)		1

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	W	N	Resolved (11SEP2020)	NOT RELATED/OTHER: blood draw			Y
2	1	W	N	Resolved (11SEP2020)	NOT RELATED/OTHER: blood draw			Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
	VACCINATION		
Withdrawn	FOLLOW-UP	11SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1122 11221026, a 24-year-old white male with no reported medical history, reported presyncope and vomiting during the prevaccination blood sample collection on 11 Sep 2020 (Day 1), which resolved that same day. The subject was withdrawn from the study before study vaccination on 11 Sep 2020 because of the presyncope and vomiting. In the opinion of the investigator, there was no reasonable possibility that the presyncope and vomiting were related to the study intervention, but rather related to the blood sample collection.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	American Indian or Alaska	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	75.6 kg	28.1 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1988	Present
Astigmatism	Astigmatism	2014	Present
Vitamin D Deficiency	Vitamin D deficiency	2015	Past
Depression	Depression	JAN2016	Past
Cholelithiasis	Cholelithiasis	JUN2016	Present
Cellulitis - Diffuse	Cellulitis	MAR2019	Past
Trichomoniasis	Trichomoniasis	JAN2020	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30JUL2020 (1)	17:46

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Arthralgia	joint pain	31JUL2020 (2)		ONGOING		
2	NERV	Headache	Headache	15SEP2020 (48)		ONGOING		
3	NERV	Headache	headache	03AUG2020 (5)		16AUG2020 (18)		14
4	GENRL	Influenza like illness	Flu like symptoms	26SEP2020 (59)		ONGOING		
5	PSYCH	Insomnia	Insomnia	22AUG2020 (24)		ONGOING		
6	PSYCH	Schizophrenia	Schizophrenia	22AUG2020 (24)		ONGOING		
7	INFEC	Sinusitis	Sinus infection	04AUG2020 (6)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Yes	Study Treatment	1	2	N
2	1	TC	N	Yes	NOT RELATED/OTHER: viral	1	48	N
3	3	TC	N	Resolved (16AUG2020)	Study Treatment	1	5	N
4	1	N	N	Yes	NOT RELATED/OTHER: viral	1	59	N
5	1	TC	N	Yes	NOT RELATED/OTHER: mental disease	1	24	N

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	1	TC/P	N	Yes	NOT RELATED/OTHER: mental disease	1	24	Y
7	2	TC	N	Yes	NOT RELATED/OTHER: bacterial	1	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30JUL2020	
Withdrawn	VACCINATION	17SEP2020	PHYSICIAN DECISION
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1127 11271022, a 38-year-old American Indian or Alaska male with a pertinent medical history of depression (in Jan 2016), received Dose 1 on 30 Jul 2020. The subject reported schizophrenia and insomnia on 22 Aug 2020, 23 days after receiving Dose 1. The subject was withdrawn from the study on 17 Sep 2020 because of the physician's decision. In the opinion of the investigator, there was no reasonable possibility that the schizophrenia was related to the study intervention, but rather it was considered to be related to an ongoing psychiatric disease.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.3 cm	119.1 kg	36.6 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seafood Allergy	Food allergy	1975	Present
Allergic Rhinitis	Rhinitis allergic	1975	Present
Acid Reflux	Gastrooesophageal reflux disease	1982	Present
Tonsillectomy	Tonsillectomy	1992	Past
Tonsillitis	Tonsillitis	1992	Past
Appendectomy	Appendicectomy	1993	Past
Appendicitis	Appendicitis	1993	Past
Essential Tremor	Essential tremor	2010	Present
Hypertension	Hypertension	2017	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	15:54

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Hypertension	Worsening of Hypertension	04SEP2020 (22)	12:15	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/P	N	Yes	NOT RELATED/OTHER: History of Hypertension	1	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Withdrawn	VACCINATION	19OCT2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	19OCT2020	PHYSICIAN DECISION

Narrative Comment
Subject C4591001 1133 11331170, a 55-year-old white male with a pertinent medical history of hypertension (since 2017), received Dose 1 on 14 Aug 2020. The subject experienced worsening of hypertension on 04 Sep 2020, 21 days after receiving Dose 1. The subject was discontinued from the study intervention on 19 Oct 2020 because of the worsening of hypertension that was ongoing at the time of the last available report. The subject was withdrawn from the study on 19 Oct 2020 because of physician's decision. In the opinion of the investigator, there was no reasonable possibility that the worsening of hypertension was related to the study intervention, but rather it was related to a history of hypertension.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156.21 cm	57.73 kg	23.6 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillitis	Tonsillitis	1990	Past
tonsillectomy	Tonsillectomy	1993	Past
anxiety	Anxiety	2000	Present
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2000	Present
cholecystectomy	Cholecystectomy	2008	Past
allergic rhinitis	Rhinitis allergic	2010	Present
breast cancer	Breast cancer	2016	Past
bilateral mastectomy	Mastectomy	2017	Past
post menopausal	Postmenopause	2017	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	16:10

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Abdominal discomfort	upset stomach	25AUG2020 (2)		21SEP2020 (29)	
2	GASTR	Diarrhoea	diarrhea	25AUG2020 (2)		25AUG2020 (2)	
3	GASTR	Diarrhoea	loose stools	25AUG2020 (2)		21SEP2020 (29)	
4	EYE	Eye pain	right eye pain	25AUG2020 (2)		21SEP2020 (29)	
5	GENRL	Fatigue	fatigue	25AUG2020 (2)		21SEP2020 (29)	
6	NERV	Headache	headache	25AUG2020 (2)		25AUG2020 (2)	
7	NERV	Headache	headache	25AUG2020 (2)		25AUG2020 (2)	
8	MUSC	Muscular weakness	muscle weakness	25AUG2020 (2)		21SEP2020 (29)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	28	2	TC/P	N	Resolved (21SEP2020)	Study Treatment	1	2	Y
2	1	1	P	N	Resolved (25AUG2020)	Study Treatment	1	2	Y
3	28	2	P	N	Resolved (21SEP2020)	Study Treatment	1	2	Y

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	28	2	P	N	Resolved (21SEP2020)	Study Treatment	1	2	Y
5	28	2	P	N	Resolved (21SEP2020)	Study Treatment	1	2	Y
6	1	1	P	N	Resolved (25AUG2020)	Study Treatment	1	2	Y
7	1	2	TC/P	N	Resolved (25AUG2020)	Study Treatment	1	2	Y
8	28	2	P	N	Resolved (21SEP2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	25AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1134 11341153, a 44-year-old white female with no pertinent medical history, received Dose 1 on 24 Aug 2020. The subject reported abdominal discomfort, diarrhea (2 episodes), right eye pain, fatigue, headache (2 episodes), and muscular weakness on 25 Aug 2020, 1 day after receiving Dose 1. On 25 Aug 2020 (Day 2), the diarrhea (first episode) and headache (2 episodes) resolved and on 21 Sep 2020 (Day 29), the abdominal discomfort, diarrhea (second episode), right eye pain, fatigue, and muscular weakness resolved. The subject was discontinued from the study intervention on 25 Aug 2020 because of the abdominal discomfort, diarrhea (2 episodes), right eye pain, fatigue, headache (2 episodes) and muscular weakness and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the abdominal discomfort, diarrhea (2 episodes), right eye pain, fatigue, headache (2 episodes), and muscular weakness were related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	79.18 kg	31.4 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hospitalization for childbirth	Delivery	2015	Past
hospitalization for childbirth	Delivery	2017	Past
headache	Headache	2018	Present
stress induced muscle pain in back	Back pain	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	11:05

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chest discomfort	CHEST TIGHTNESS	30AUG2020 (5)		06SEP2020 (12)		8
2	NERV	Headache	WORSENING HEADACHE	27AUG2020 (2)		03SEP2020 (9)		8
3	METAB	Hypokalaemia	HYPOKALEMIA	30AUG2020 (5)		01SEP2020 (7)		3
4	GENRL	Injection site pain	PAIN AT INJECTION SITE	26AUG2020 (1)		30AUG2020 (5)		5
5	MUSC	Pain in extremity	ARM PAIN (LEFT)	28AUG2020 (3)		02SEP2020 (8)		6

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (06SEP2020)	Study Treatment	1	5	N
2	2	TC/P	N	Resolved (03SEP2020)	Study Treatment	1	2	Y
3	1	TC	N	Resolved (01SEP2020)	NOT RELATED/OTHER: IDIOPATHIC	1	5	N
4	3	P	N	Resolved (30AUG2020)	Study Treatment	1	1	Y
5	3	TC/P	N	Resolved (02SEP2020)	Study Treatment	1	3	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	30AUG2020	ADVERSE EVENT
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1134 11341174, a 36-year-old white female with a pertinent medical history of headache (since 2018), received Dose 1 on 26 Aug 2020. The subject reported severe injection site pain on 26 Aug 2020, after Dose 1 administration, worsening headache on 27 Aug 2020, 1 day after receiving Dose 1, and severe pain in extremity (left arm), 2 days after receiving Dose 1. On 30 Aug 2020 (Day 5), the injection site pain resolved. On 02 Sep 2020 (Day 8), the pain in extremity resolved and on 03 Sep 2020 (Day 9), the worsening headache resolved. The subject was discontinued from the study intervention on 30 Aug 2020 because of the injection site pain, worsening headache, and pain in extremity and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the injection site pain, worsening headache, and pain in extremity were related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.78 cm	91.82 kg	29.3 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Peritonsillar abscess	Peritonsillar abscess	1984	Past
(+) purified protein derivative	Tuberculin test positive	1984	Past
Idiopathic Urticaria	Idiopathic urticaria	2008	Present
Deviated septum repair	Nasal septal operation	2009	Past
Fever of Unknown Origin	Pyrexia	2012	Past
High cholesterol	Blood cholesterol increased	JAN2012	Present
hypertension	Hypertension	JAN2012	Present
GERD	Gastrooesophageal reflux disease	AUG2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	15:01

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	SKIN	Urticaria	urticaria	13AUG2020 (10)		13AUG2020 (10)		1	2	TC/P/W	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (13AUG2020)	NOT RELATED/OTHER: idiopathic urticaria (pre-existing on med hx)	1	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Withdrawn	VACCINATION	22SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	22SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1140 11401035, a 62-year-old white male with a pertinent medical history of idiopathic urticaria (since 2008), received Dose 1 on 04 Aug 2020. The subject reported urticaria on 13 Aug 2020, 9 days after receiving Dose 1. On 13 Aug 2020 (Day 10), the urticaria resolved. The subject was withdrawn from the study on 22 Sep 2020 because of the urticaria. In the opinion of the investigator, there was no reasonable possibility that the urticaria was related to the study intervention, but rather it was related to idiopathic urticaria (a pre-existing medical history).

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.4 cm	82 kg	23.3 kg/m2	22OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	1971	Present
acid reflux	Gastrooesophageal reflux disease	1988	Past
left tarsal bone fracture, foot	Foot fracture	2002	Past
left avulsion fracture, foot	Avulsion fracture	2007	Past
fundal plication	Oesophagogastric fundoplasty	2007	Past
eye allergies	Eye allergy	2010	Present
osteoarthritis, both knees	Osteoarthritis	2016	Present
hypothyroidism	Hypothyroidism	2018	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22OCT2020 (1)	16:23

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Amnesia	short term memory loss	07NOV2020 (17)	19:00	10NOV2020 (20)	08:00	4	1
2	NERV	Paraparesis	working diagnosis was spastic paraparesis	07NOV2020 (17)	14:00	ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN/P	Y	Resolved (10NOV2020)	NOT RELATED/OTHER: unknown at this time	1	17	Y
2	TC/TCN/P	Y	Yes	NOT RELATED/OTHER: Unknown at this time	1	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22OCT2020	
Withdrawn	VACCINATION	13NOV2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1140 11401306, a 53-year-old white male with a pertinent medical history of hypothyroidism (since 2018) and left leg weakness (since Sep 2020), received Dose 1 on 22 Oct 2020. The subject reported amnesia (short term memory loss) and paraparesis on 07 Nov 2020, 16 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of amnesia and paraparesis included omeprazole (since 2007) for acid reflux prevention, olopatadine hydrochloride eye drops (since 2010) for eye allergies, and levothyroxine (since 2018) for hypothyroidism. On 07 Nov 2020 (Day 17), the subject visited the emergency room because of a sudden onset of change in visual perception, short term memory loss, and chronic spastic paraparesis. He was hospitalized for further blood work-up, a lumbar puncture, and imaging studies. A blood test on the same day (Day 17) showed C-reactive protein of 2.1 mg/L (upper limit of normal [ULN]: <8 mg/L), blood copper of 96 µg/dL (normal range [NR]: 72 – 166 µg/dL), blood folate of 10.47 ng/mL (lower limit of normal: 4.77 ng/mL), and vitamin B12 of 753 pg/mL (NR: 211 – 946 pg/mL). A nonenhanced head computed tomography showed no intracranial hemorrhage or acute territorial infarction. There was a mild asymmetry of the lateral ventricles with dilatation of the atrium of the right lateral ventricle; however, the remainder of the ventricles were normal in size and configuration. The basal cisterns and foramen magnum were patent and there were no depressed calvarial fractures. The extracranial soft tissue structures were unremarkable, and the paranasal sinuses and mastoid air cells were clear. A computed angiography (CTA) of the head showed that the intracranial segments of the

Narrative Comment
internal carotid arteries and basilar, anterior, middle, and posterior cerebral arteries were patent without flow-limiting stenosis. No aneurysm or arteriovenous malformation was visualized. The CTA of the neck showed conventional branching of the great vessels from the aortic arch. The origins of the great vessels and vertebral arteries were patent. There was no occlusion of the common carotid, external carotid, cervical segments of the internal carotid arteries, or the cervical segments of the vertebral arteries. The vertebral arteries were codominant. The imaging results of lungs, thyroid, and bones were unremarkable. A magnetic resonance imaging (MRI) of the brain to evaluate possible encephalitis in comparison with CTA of head performed on 07 Nov 2020 (Day 17) showed no abnormal signal intensity within the brain parenchyma. A developmental venous anomaly was observed in the right frontal lobe. There was asymmetric enlargement of the atrium and occipital horn of the right lateral ventricle. There were no intraventricular masses seen and the basal cisterns were patent. No acute intracranial hemorrhage, evidence of acute infarction, space-occupying mass, shift of the midline structures, or any abnormal extra-axial fluid collections were observed. The pituitary gland was not enlarged and the pineal and cervico-medullary regions were normal. Normal flow voids of the major intracranial arterial vessels were observed and there was no abnormal enhancement following contrast administration. Mild mucosal thickening was present in the maxillary, ethmoid, sphenoid, and frontal sinuses. On 08 Nov 2020 (Day 18), the subject was seen by a neurologist, at which time the subject reported the symptoms of mental fogginess associated with visual changes that was described as poor depth perception. He also reported subtle unsteadiness and admitted to having a longer history of clumsiness. On examination, he was noted to have mild spasticity in the legs, brisk reflexes in the legs, and bilateral Babinski sign. His gait was slightly abnormal due to subtle circumduction of the right leg and he had mild issues with tandem gait. On 08 Nov 2020 (Day 18), a syphilis IgM/IgG screen test (*Treponema* test) was nonreactive and the human T-lymphotropic virus-1/-2 antibody test was negative. Autoimmune work-up performed on the same day (Day 18) was within normal limits with centromere antibody of 4 AU/mL (NR: 0-99 AU/mL), double-stranded deoxyribonucleic acid of 9 AU/mL (NR: 0-99 AU/mL), histone antibody of 16 AU/mL (NR: 0-99 AU/mL), JO-1 autoantibody of 5 AU/mL (NR: 0-99 AU/mL), ribonucleoprotein autoantibody of 31 U/mL (NR: 0-99 U/mL), scleroderma-70 autoantibody of 15 AU/mL (NR: 0-99 AU/mL), Smith autoantibody of 10 AU/mL (NR: 0-99 AU/mL), Sjogren's syndrome-A (SSA) autoantibody of 35 AU/mL (NR: 0-99 AU/mL), SSB autoantibody of 10 AU/mL (NR: 0-99 AU/mL), and GAD-65 autoantibody of <5.0 U/mL (NR: 0.0-5.0 U/mL). On 10 Nov 2020 (Day 20), the hepatitis panel (hepatitis A, B, and C virus) and human immunodeficiency virus (antigen/antibody combo) tests were nonreactive. An MRI of the cervical spine was performed for possible transverse myelitis, which showed no evidence of transverse myelitis or other acute or chronic process in the spinal cord. Mild multilevel spinal canal stenosis secondary to disc bulging and small disc protrusions were present at C2-C3 and C4-C5 through C6-C7. There was no spinal cord impingement or diffuse degenerative disc desiccation noted. An MRI of the thoracic spine was obtained with and without gadolinium contrast for possible myelopathy, which revealed minimal to mild degenerative changes in the thoracic spine. Vertebral body heights were maintained, and the bone marrow signals were within normal limits. No spondylolisthesis or high-grade central canal or neural foraminal stenosis was observed. The spinal cord demonstrated normal signal intensity. No evidence of abnormal enhancement was noted. There were no intradural or extradural masses, and the paraspinal soft tissues were unremarkable. On the same day (Day 20), a lumbar puncture was performed and the cerebrospinal fluid (CSF) analysis showed clear and colorless CSF with a red blood cell count of 114/µL (ULN: <2/µL), total nucleated cells of <3/µL (ULN: <5/µL); white blood cell count of 3+, CSF glucose of 66, and protein of 51 (units and normal ranges not provided). The Gram stain showed no organisms and culture results showed no growth for 5 days. The amnesia was considered resolved on 10 Nov 2020 (Day 20). On 11 Nov 2020 (Day 21), the subject reported that he might have had mild injection site discomfort for 3 days after receiving Dose 1; however, he did not report it to the site at that time. The subject remained hospitalized at the time of this report. The subject was discontinued from the study intervention on 13 Nov 2020 because of the amnesia and paraparesis and remains in the study to be evaluated for safety, immunogenicity, and efficacy. The paraparesis was ongoing at the time of the last available report.

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Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the amnesia and paraparesis were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment and considered the amnesia and paraparesis as coincidental and associated with underlying neurological conditions.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	72.82 kg	25.1 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	13:17

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GASTR	Abdominal pain	Abdominal Pain	26AUG2020 (10)		05OCT2020 (50)	
2	SKIN	Night sweats	Night sweats	29AUG2020 (13)		ONGOING	

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	41	2	P	N	Resolved (05OCT2020)	Study Treatment	1	10	Y
2		3	P	N	Yes	Study Treatment	1	13	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Withdrawn	VACCINATION	04SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1142 11421111, a 61-year-old white male with a pertinent medical history of hypothyroidism (since 2015), received Dose 1 on 17 Aug 2020. The subject reported abdominal pain on 26 Aug 2020 and night sweats on 29 Aug 2020, 9 and 12 days after receiving Dose 1; respectively. The subject was discontinued from the study intervention on 04 Sep 2020 because of the abdominal pain and night sweats and remains in the study to be evaluated for safety, immunogenicity, and efficacy. The abdominal pain resolved on 05 Oct 2020 and night sweats were ongoing at the time of the last available report. In the opinion of the investigator, there was a reasonable possibility that the abdominal pain and night sweats were related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	74.09 kg	23.4 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SHOULDER PAIN	Arthralgia	2015	Present
SHINGLES VACCINE DOSE 1 [vaccination]	Herpes zoster immunisation	13FEB2020	Past
SHINGLES VACCINE DOSE 2 [vaccination]	Herpes zoster immunisation	25JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	12:30

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Parkinsonism	parkinsonism	18SEP2020 (15)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	P	N	Yes	NOT RELATED/OTHER: natural progression of parkinsonism	1	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flu shot	INFLUENZA VACCINE	06OCT2020

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Withdrawn	VACCINATION	21SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1145 11451076, a 64-year-old Asian male with no pertinent medical history, received Dose 1 on 04 Sep 2020. The subject was diagnosed with Parkinsonism on 18 Sep 2020, 14 days after receiving Dose 1. The subject was discontinued from the study intervention on 21 Sep 2020 because of the Parkinsonism that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the Parkinsonism was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
153.67 cm	67.36 kg	28.5 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left breast cancer	Breast cancer	1991	Past
allergy to adhesive tape	Dermatitis contact	1991	Present
hypertension	Hypertension	1991	Present
melanoma left arm	Malignant melanoma	1991	Past
left breast mastectomy	Mastectomy	1991	Past
melanoma left arm excised	Skin neoplasm excision	1991	Past
hypothyroid	Hypothyroidism	1992	Present
allergy to codeine	Drug hypersensitivity	1993	Present
osteoporosis	Osteoporosis	1993	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
varicose veins	Varicose vein	2000	Present
right upper quadrant pain	Abdominal pain upper	2003	Past
cholecystectomy	Cholecystectomy	2003	Past
insomnia	Insomnia	2010	Present
multiple lipomas	Lipoma	2012	Past
lipomas excised	Lipoma excision	2012	Past
angina	Angina pectoris	2013	Present
rheumatoid arthritis	Rheumatoid arthritis	2017	Present
anxiety	Anxiety	2018	Present
depression	Depression	2018	Present
Type II diabetes	Type 2 diabetes mellitus	2018	Present
urinary incontinence	Urinary incontinence	FEB2019	Present
cataract right eye	Cataract	MAR2019	Past
cataract surgery right eye	Cataract operation	MAR2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	12:18

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Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Dysgeusia	sour taste	06SEP2020 (3)		10SEP2020 (7)		5	2
2	GENRL	Injection site induration	injection site induration	05SEP2020 (2)		07SEP2020 (4)		3	1
3	GENRL	Injection site pain	injection site tenderness	05SEP2020 (2)		07SEP2020 (4)		3	1
4	MUSC	Muscle spasms	back muscle spasms	04SEP2020 (1)	16:01	05SEP2020 (2)		2	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (10SEP2020)	Study Treatment	1	3	N
2	N	N	Resolved (07SEP2020)	Study Treatment	1	2	N
3	N	N	Resolved (07SEP2020)	Study Treatment	1	2	N
4	P	N	Resolved (05SEP2020)	NOT RELATED/OTHER: likely postural/trauma	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Withdrawn	VACCINATION	11SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521359, a 68-year-old white female with pertinent medical history of osteoporosis (since 1993), rheumatoid arthritis (since 2017), and anxiety and type 2 diabetes mellitus (both since 2018), received Dose 1 on 04 Sep 2020. The subject was diagnosed with muscle spasms (back muscle spasms) on 04 Sep 2020, after receiving Dose 1. On 05 Sep 2020 (Day 2), the muscle spasms resolved. On the same day (Day 2), the subject experienced injection site induration and injection site pain. On 06 Sep 2020 (Day 3), the subject experienced dysgeusia. On 07 Sep 2020 (Day 4), the injection site induration and injection site pain resolved and dysgeusia resolved on 10 Sep 2020 (Day 7). The subject was discontinued from the study intervention on 11 Sep 2020 because of the muscle spasms and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the muscle spasms were related to the study intervention, but rather they were related to poor posture over time.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
149.86 cm	58.91 kg	26.2 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Penicillin Allergy	Drug hypersensitivity	1970	Present
allergy to black olives	Food allergy	1975	Present
Aspirin Allergy	Drug hypersensitivity	1985	Present
Breast Surgery for Fibrocystic Removal (right)	Breast cyst excision	1990	Past
Fibrocystic Right Breast	Fibrocystic breast disease	1990	Past
Gall Bladder Removal	Cholecystectomy	2001	Past
Gall Bladder Stones	Cholelithiasis	2001	Past
Breast Surgery for Fibrocystic Removal (left)	Breast cyst excision	2005	Past
Fibrocystic Left Breast	Fibrocystic breast disease	2005	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	09:33

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	EAR	Deafness unilateral	hearing loss right ear	14OCT2020 (20)		23OCT2020 (29)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	10	3	P	N	Resolved (23OCT2020)	Study Treatment	1	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Withdrawn	VACCINATION	15OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521476, a 61-year-old white female with no pertinent medical history, received Dose 1 on 25 Sep 2020. The subject was diagnosed with unilateral deafness (right ear) on 14 Oct 2020, 19 days after receiving Dose 1. The subject was discontinued from the study intervention on 15 Oct 2020 because of the unilateral deafness and remains in the study to be evaluated for safety, immunogenicity, and efficacy. On 23 Oct 2020 (Day 29), the unilateral deafness resolved. In the opinion of the investigator, there was a reasonable possibility that the unilateral deafness was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	72	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	78.27 kg	25.1 kg/m2	07OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lithotripsy	Lithotripsy	1999	Past
nephrolithiasis	Nephrolithiasis	1999	Past
allergy to celery	Food allergy	2000	Present
allergy to mango	Food allergy	2000	Present
hearing loss	Deafness	2010	Present
osteoarthritis	Osteoarthritis	2010	Present
Type II diabetes	Type 2 diabetes mellitus	2010	Present
hypertension	Hypertension	2018	Present
prostatism	Prostatism	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07OCT2020 (1)	12:52

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Syncope	vasovagal syncope	26OCT2020 (20)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/TCN/P	Y	Resolved ()	NOT RELATED/OTHER: Unknown	1	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07OCT2020	
Withdrawn	VACCINATION	06NOV2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1152 11521497, a 72-year-old white male with a pertinent medical history of type 2 diabetes mellitus (since 2010) and hypertension (since 2018), received Dose 1 on 07 Oct 2020. The subject reported syncope on 26 Oct 2020, 19 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of syncope included metformin (since 2013) for diabetes, ibuprofen (since 2015) for osteoarthritis, lisinopril (since 2018) for hypertension, and doxazosin (since 2019) for benign prostatic hypertrophy. The subject missed Visit 2 on 28 Oct 2020 (Day 22). On 06 Nov 2020 (Day 31), it was reported that the subject was admitted to the hospital on 26 Oct 2020 (Day 20) since he fainted in the middle of the night. The subject was transferred to the intensive care unit. Family medical history relevant to the syncope was unknown. The subject tested negative for COVID-19 at the hospital. On an unspecified date, the syncope resolved and the subject was discharged from the hospital. The subject was discontinued from the study intervention on 06 Nov 2020 and remains in the study to be evaluated for safety, immunogenicity, and efficacy. During the follow-up, the site contacted the subject's sister, who confirmed that the subject died on 11 Nov 2020. The cause of death was reported as unknown. It was not reported if an autopsy was performed. A death certificate might be available at a later date. In the opinion of the investigator, there was no reasonable possibility that the syncope was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the syncope was most likely coincidental and associated with underlying clinical conditions.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	25	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.8 cm	69.1 kg	23.4 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seafood Allergy	Food allergy	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	16:05

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Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	21AUG2020 (1)	12:25	ONGOING				P	N

Adverse Events				
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: THERE IS NOT AN UNDERLYING CAUSE. THIS EVENT IS A STANDARD PREGNANCY.	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Withdrawn	VACCINATION	28SEP2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1156 11561015, a 25-year-old black or African American female with no pertinent medical history, received Dose 1 on 21 Aug 2020. The subject had an exposure during pregnancy on 21 Aug 2020, the day of receiving Dose 1. On 28 Sep 2020, the subject's exposure during pregnancy was reported. The subject's first day of her last menstrual period was 04 Aug 2020. The estimated date of conception was 21 Aug 2020, which was also the same day of initial exposure. The mother did not smoke, drink alcohol, or use illicit drugs. The subject had 5 previous pregnancies and 5 other children. The father was 23 years old and was unemployed. The subject underwent laboratory tests and procedures that included urine human chorionic gonadotropin on 28 Sep 2020, which was positive. The subject was discontinued from the study intervention on 28 Sep 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator considered there was not a reasonable possibility that the exposure during pregnancy was related to the study intervention or clinical trial procedures. Causality with concomitant drugs was not applicable.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	30	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	69.55 kg	26.3 kg/m2	07AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	12:19

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1			UPPER BODYRASH DUE TO VACCINE	08AUG2020 (2)	08:00	25AUG2020 (19)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	18	2	TC/P	N	Resolved (25AUG2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Withdrawn	VACCINATION	08AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1163 11631059, a 30-year-old white female with no reported medical history, received Dose 1 on 07 Aug 2020. The subject developed an upper body rash due to vaccine on 08 Aug 2020, 1 day after receiving Dose 1. The subject was discontinued from the study intervention on 08 Aug 2020 because of the upper body rash due to vaccine and remains in the study to be evaluated for safety, immunogenicity, and efficacy. The upper body rash due to vaccine was considered resolved on 25 Aug 2020 (Day 19). In the opinion of the investigator, there was a reasonable possibility that the upper body rash due to vaccine was related to the study.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.3 cm	60.7 kg	19.3 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Flat feet	Foot deformity	1980	Present
Scoliosis	Scoliosis	1980	Present
Smoker	Tobacco user	1988	Present
Left leg femoral artery repair	Arterial repair	2011	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	14:56

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Dizziness	Dizziness	31AUG2020 (1)	15:30	31AUG2020 (1)	17:30

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	P	N	Resolved (31AUG2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Withdrawn	VACCINATION	31AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1166 11661047, a 50-year-old black or African American male with no pertinent medical history, received Dose 1 on 31 Aug 2020. The subject reported dizziness on 31 Aug 2020, approximately half an hour after receiving Dose 1. On 31 Aug 2020 (Day 1), the dizziness resolved. The subject was discontinued from the study intervention on 31 Aug 2020 because of the dizziness and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the dizziness was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156 cm	64 kg	26.3 kg/m2	30OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INV	Blood pressure increased	Increasing of systolic and diastolic blood pressure	30OCT2020 (1)	14:55	30OCT2020 (1)		1	2	W	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (30OCT2020)	NOT RELATED/OTHER: Blood pressure values of volunteer were high during vaccine preparation period.			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30OCT2020	
	VACCINATION		
Withdrawn	FOLLOW-UP	30OCT2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1205 12051028, a 38-year-old white male with no reported medical history, experienced increased blood pressure before administration of study vaccination on 30 Oct 2020, which resolved on the same day. The subject was withdrawn from the study before administration of study vaccination on 30 Oct 2020 because of the increased blood pressure. In the opinion of the investigator, there was no reasonable possibility that the increased blood pressure was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	75	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	65.18 kg	26.2 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	1990	Present
Parkinson's Disease	Parkinson's disease	1990	Present
Hypothyroidism	Hypothyroidism	2000	Present
Insomnia	Insomnia	2015	Present
Post-Menopausal	Postmenopause	2015	Present

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Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	13AUG2020 (1)	13:23

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	INJ&P	Ankle fracture	Lateral Malleolus Fracture - left ankle	19AUG2020 (7)		ONGOING			2	TC/TCN/P/W
2	INJ&P	Fall	FALL	19AUG2020 (7)		19AUG2020 (7)		1	2	W
3	MUSC	Muscular weakness	Diffuse weakness in extremities (Bilateral legs and Left arm)	19AUG2020 (7)		25AUG2020 (13)		7	2	W
4	NERV	Transient ischaemic attack	Suspected TIA	19AUG2020 (7)		19AUG2020 (7)		1	2	W

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Yes	NOT RELATED/OTHER: Patient fell; Pt under evaluation for suspected Transient Ischemic Attack	1	7	Y
2	N	Resolved (19AUG2020)	NOT RELATED/OTHER: Pt under evaluation for suspected Transient Ischemic Attack	1	7	Y
3	N	Resolved (25AUG2020)	NOT RELATED/OTHER: Pt under evaluation for suspected Transient Ischemic Attack	1	7	Y
4	N	Resolved (19AUG2020)	NOT RELATED/OTHER: Unknown; pt is following up with PCP	1	7	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Withdrawn	VACCINATION	25AUG2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	25AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1224 12241012, a 75-year-old white female with a pertinent medical history of Parkinson's disease (since 1990) and hypothyroidism (since 2000), received Dose 1 on 13 Aug 2020. The subject experienced a transient ischemic attack that resulted in muscular weakness (diffuse weakness in extremities [bilateral legs and left arm]), fall, and ankle fracture (lateral malleolus fracture - left ankle) on 19 Aug 2020, 6 days after receiving Dose 1. The subject was following up with her primary care physician and was under evaluation for the suspected transient ischemic attack. The subject recovered from the suspected transient ischemic attack on 19 Aug 2020 (Day 7) and the muscular weakness resolved on 25 Aug 2020 (Day 13). The subject was withdrawn from the study on 25 Aug 2020 because of the transient ischemic attack that led to muscular weakness, fall, and ankle fracture. The ankle fracture was ongoing at the time of the last available report. In the opinion of the investigator, there was no reasonable possibility that the transient ischemic attack, muscular weakness, fall, and ankle fracture were related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	30	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.43 cm	65.45 kg	22.5 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Acne	Acne	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	10:47

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Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INV	Blood pressure increased	Increased Blood Pressure	24AUG2020 (1)		10SEP2020 (18)	
2	GASTR	Diarrhoea	Diarrhea	24AUG2020 (1)		06SEP2020 (14)	
3	GENRL	Fatigue	Fatigue	24AUG2020 (1)		02SEP2020 (10)	
4	INV	Heart rate irregular	Irregular Heart Rate	24AUG2020 (1)		10SEP2020 (18)	
5	GENRL	Pyrexia	Feverish Chills	24AUG2020 (1)		02SEP2020 (10)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	18	2	N	N	Resolved (10SEP2020)	Study Treatment	1	1	N
2	14	2	N	N	Resolved (06SEP2020)	Study Treatment	1	1	N
3	10	2	N	N	Resolved (02SEP2020)	Study Treatment	1	1	N
4	18	2	P/W	N	Resolved (10SEP2020)	Study Treatment	1	1	Y
5	10	2	N	N	Resolved (02SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Withdrawn	VACCINATION	05SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	05SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1224 12241065, a 30-year-old white female with no pertinent medical history, received Dose 1 on 24 Aug 2020. The subject was diagnosed with irregular heart rate on 24 Aug 2020 after Dose 1 administration. On 24 Aug 2020 (Day 1), the subject also experienced increased blood pressure, diarrhea, fatigue, and pyrexia. The fatigue and pyrexia resolved on 02 Sep 2020 (Day 10), the diarrhea resolved on 06 Sep 2020 (Day 14), and the increased blood pressure resolved on 10 Sep 2020 (Day 18). The subject was withdrawn from the study on 05 Sep 2020 because of the irregular heart rate which resolved on 10 Sep 2020. In the opinion of the investigator, there was a reasonable possibility that the irregular heart rate was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169.5 cm	83.7 kg	29.1 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	2010	Present
Anxiety	Anxiety	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	09:52

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Adverse Events						
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)
1	MUSC	Myalgia	Muscle pain (shoulders and neck, on the right body side)	18AUG2020 (8)		ONGOING

Adverse Events										
AE Number	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			2	TC/P	N	Yes	Study Treatment	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Withdrawn	VACCINATION	01SEP2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1226 12261072, a 42-year-old white female with a pertinent medical history of hypothyroidism (since 2010) and anxiety (since 2016), received Dose 1 on 11 Aug 2020. The subject reported myalgia on 18 Aug 2020, 7 days after receiving Dose 1. The subject was discontinued from the study intervention on 01 Sep 2020 because of the myalgia that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the myalgia was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	27	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	53.9 kg	20.5 kg/m2	28SEP2020 (-1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
C-Section	Caesarean section	08OCT2015	Past
Preeclampsia	Pre-eclampsia	08OCT2015	Past
HIV	HIV test positive	SEP2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29SEP2020 (1)	13:54

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during Pregnancy	20OCT2020 (22)	10:25	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: Pregnancy	1	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29SEP2020	
Withdrawn	VACCINATION	20OCT2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1230 12301045, a 27-year-old black or African American female with pertinent obstetrical history of 1 previous pregnancy with a live birth requiring cesarean section due to pre-eclampsia (on 08 Oct 2015) and positive human immunodeficiency virus test (since Sep 2018), received Dose 1 on 29 Sep 2020. The subject reported exposure during pregnancy on 20 Oct 2020, 21 days after receiving Dose 1. Concomitant medications reported 2 weeks prior to the exposure during pregnancy included dolutegravir sodium/lamivudine/tenofovir disoproxil fumarate (Acriptega) for human immuno deficiency virus infection (since Sep 2018) and norethisterone for contraception (since Sep 2019). On 28 Sep 2020, the subject's pregnancy test at Visit 1 was negative prior to receiving Dose 1. On 20 Oct 2020 (Day 22), during Visit 2, the subject's pregnancy test was positive. She had confirmed the use of contraceptives (norethisterone and use of condom by partner). The subject's first day of last menstrual period approximately around 01 Sep 2020. The gestational age at the time of initial exposure was first trimester. It was reported that the subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. However, it was also reported that during the pregnancy, the subject's partner smoked (10 per day) and drank alcohol (20 units per week) with no usage of illicit drugs. The subject was discontinued from the study intervention on 20 Oct 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the exposure during pregnancy was related to the study intervention, concomitant medications, or clinical trial procedures.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
188 cm	54.25 kg	15.3 kg/m2	15AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Syncope	Syncope	15AUG2020 (1)	15:40	15AUG2020 (1)	15:41	1	2
2	GASTR	Vomiting	vomits	15AUG2020 (1)	15:30	15AUG2020 (1)	15:40	1	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TCN/P/W	N	Resolved (15AUG2020)	NOT RELATED/OTHER: post phlebotomy			Y
2	TCN/P/W	N	Resolved (15AUG2020)	NOT RELATED/OTHER: post sincopal recovery			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
	VACCINATION		
Withdrawn	FOLLOW-UP	25SEP2020	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 1231 12311409, a 38-year-old white male with no reported medical history, experienced syncope and vomiting after the prevaccination phlebotomy on 15 Aug 2020 (Day 1), which resolved on the same day. Study vaccination was not administered. The subject requested withdrawal from the study on 25 Sep 2020 because of the syncope and vomiting. In the opinion of the investigator, there was no reasonable possibility that the syncope and vomiting were related to the study intervention, but rather they were related to the phlebotomy.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	77 kg	25.4 kg/m2	18AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Syncope	Syncope	18AUG2020 (1)	10:25	18AUG2020 (1)	13:30	1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	W	N	Resolved (18AUG2020)	NOT RELATED/OTHER: Post blood extraction			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	

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FDA-CBER-2021-5683-1787617

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	VACCINATION		
Withdrawn	FOLLOW-UP	18AUG2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1231 12311926, a 32-year-old white male with no reported medical history, reported syncope during the prevaccination blood sample collection on 18 Aug 2020 (Day 1); the syncope resolved on the same day. The subject was withdrawn from the study before study vaccination on 18 Aug 2020 because of the syncope. In the opinion of the investigator, there was no reasonable possibility that the syncope was related to the study intervention, but rather it was related to blood sample collection.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	91 kg	32.2 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lung adenocarcinoma	Lung adenocarcinoma	01JUL2019	Past
Depressive syndrome	Depression	01OCT2019	Present
Hypothyroidism	Hypothyroidism	13DEC2019	Present
Thyroidectomy	Thyroidectomy	13DEC2019	Past
Left Lobectomy	Exeresis	07JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	14:58

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Metastases to central nervous system	Brain metastasis	28AUG2020 (9)		ONGOING			1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/P	Y	Yes	NOT RELATED/OTHER: history of primary lung adenocarcinoma	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Withdrawn	VACCINATION	28AUG2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12312577, a 46-year-old white female with a medical history of lung adenocarcinoma (from 01 Jul 2019 to 07 Jan 2020; left lobectomy on 07 Jan 2020), depression (since 01 Oct 2019), hypothyroidism (since 13 Dec 2019), and thyroidectomy (benign nodule; on 13 Dec 2019), received Dose 1 on 20 Aug 2020. The subject was diagnosed with brain metastasis on 28 Aug 2020, 8 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the onset of the brain metastasis included quetiapine (since 01 Oct 2019) for depressive disorder, and levothyroxine (since 13 Dec 2019) for hypothyroidism. The subject was discontinued from the study intervention on 28 Aug 2020 because of the brain metastasis due to lung adenocarcinoma and remains in the study to be evaluated for safety, immunogenicity, and efficacy. On 10 Sep 2020 (Day 22), during Visit 2 at the study site, the subject reported that a routine brain computerized tomogram performed on 28 Aug 2020 (Day 9) revealed an abnormal brain image finding; however, the details of the imaging were not available at that time. On 18 Sep 2020 (Day 30), the subinvestigator contacted the subject for additional information, and the subject confirmed that a gadolinium magnetic resonance imaging (MRI) - spectroscopy that was performed on 08 Sep 2020 (Day 20) revealed 2 focal images in the right hemisphere and 1 in the right cerebellum hemisphere that were not present in the previous MRI. These lesions were considered as a secondary proliferative etiology of the primary tumor (lung adenocarcinoma in Jul 2019). The subject's oncologist suggested brain radiosurgery for the treatment of the brain metastasis. During a follow-up call by the subinvestigator on 06 Oct 2020 (Day 48), the subject reported that he received radiosurgery therapy (daily course) and dexamethasone treatment 8 mg once daily (QD) on 05 Oct 2020 (Day 47), followed by 4 mg QD until 09 Oct 2020 (Day 51) for the brain metastasis. The subject tolerated the procedure well. The subject remained asymptomatic and the brain metastasis was ongoing at the time of the last available report. The investigator considered the brain metastasis to be a medically significant event. In the opinion of the investigator, there was no reasonable possibility that the brain metastasis was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was suspected to be related to secondary disease from lung adenocarcinoma diagnosed in Jul 2019. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182 cm	83.5 kg	25.2 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	18:50
2	BNT162b2	09SEP2020 (20)	14:00

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	PSYCH	Anxiety	severe anxiety	23SEP2020 (34)	23:00	14OCT2020 (55)	15:30	22
2	GENRL	Injection site pain	mild pain at the injection site	23AUG2020 (3)	11:17	25AUG2020 (5)	14:47	3
3	INFEC	Suspected COVID-19	Suspected COVID-19 Illness	09SEP2020 (20)	21:00	14SEP2020 (25)	11:00	6

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	W	N	Resolved (14OCT2020)	NOT RELATED/OTHER: constitutive features	2	15	Y
2	1	N	N	Resolved (25AUG2020)	Study Treatment	1	3	N
3	3	TC	Y	Resolved (14SEP2020)	NOT RELATED/OTHER: unknown	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Withdrawn	VACCINATION	23SEP2020	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	23SEP2020	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 1231 12312982, a 36-year-old white male with no reported medical history, received Dose 1 on 21 Aug 2020 and Dose 2 on 09 Sep 2020 (Day 20). The subject reported severe anxiety on 23 Sep 2020, 14 days after receiving Dose 2. On 09 Sep 2020 (Day 20), the subject presented to the emergency room (ER) with fever (body temperature of 39.3˚centigrade [C]), malaise, myalgias, headache and nausea. The subject had a serious adverse event of suspected COVID-19 reported on 09 Sep 2020 (Day 20) and was treated with clonixin lysinate/pargeverine hydrochloride 10 mg/125 mg for nausea since 09 Sep 2020 (Day 20). On the same day night (Day 20), the subject presented again to the ER afebrile (body temperature of 39˚C), eupneic and had normal oxygen saturation with persistent moderate malaise, nausea and headache. On 10 Sep 2020 (Day 21), the subject remained subfebrile, with nausea and reported dizziness and darker urine colour. In the context of the severe acute respiratory syndrome (SARS) CoV2 pandemic, the physician decided to evaluate whether these symptoms were associated with SARS CoV2 infection and requested a SARS CoV2 reverse transcription polymerase chain reaction test, which was negative; laboratory tests results were normal and unremarkable except for mild increase in creatinine of 1.21 (unit and normal range not reported), abdominal ultrasound showed no significant findings and was unremarkable, and chest x-ray showed right paracardiac opacity and a possible right lung consolidation. On 12 Sep 2020 (Day 23), a chest x-ray showed bilateral pneumonia and the subject was hospitalized. A chest computerized tomogram scan was unremarkable and urine analysis reports were normal. On 13 Sep 2020 (Day 24), the symptoms fever, myalgia, headache, fatigue and nausea resolved during hospitalization. The COVID disease and pneumonia were ruled out and there were no other etiological causes identified for the symptoms that the subject had. The subject remained isolated in-house for suspected COVID-19 despite presenting no further fever and improving symptoms. On 14 Sep 2020 (Day 25), the suspected COVID-19 resolved and the subject was discharged from the hospital. The anxiety occurred after this hospitalization. On 14 Oct 2020 (Day 55), the anxiety resolved. The subject requested withdrawal from the study on 23 Sep 2020. In the opinion of the investigator, there was no reasonable possibility that the anxiety and suspected COVID-19 were related to the study intervention; anxiety was considered related to constitutive features and COVID-19 was suspected as a reactogenic systemic event. Pfizer concurred with the investigator's causality assessment for suspected COVID-19

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156 cm	54 kg	22.2 kg/m2	30AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30AUG2020 (1)	10:34

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Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Injection site pain	pain at injection site	30AUG2020 (1)	10:34	16SEP2020 (18)	09:00

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	18	2	TC/P/W	N	Resolved (16SEP2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30AUG2020	
Withdrawn	VACCINATION	05OCT2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	05OCT2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1231 12315429, a 37-year-old white female with no reported medical history, received Dose 1 on 30 Aug 2020. The subject reported moderate injection site pain on 30 Aug 2020, after Dose 1 administration. The injection site pain resolved on 16 Sep 2020 (Day 18). The subject was withdrawn from the study on 05 Oct 2020 because of the injection site pain. In the opinion of the investigator, there was a reasonable possibility that the injection site pain was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	50 kg	19.1 kg/m2	30AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 Diabetes	Type 2 diabetes mellitus	30AUG2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30AUG2020 (1)	11:32

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Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	PSYCH	Depression	depressive syndrome	10SEP2020 (12)	13:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/P	N	Yes	NOT RELATED/OTHER: unknown	1	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30AUG2020	
Withdrawn	VACCINATION	22OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12315441, a 34-year-old white female with no pertinent medical history, received Dose 1 on 30 Aug 2020. The subject reported depression on 10 Sep 2020, 11 days after receiving Dose 1. The subject was discontinued from the study intervention on 22 Oct 2020 because of the depression that was ongoing as of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the depression was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	23	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	108.18 kg	43.5 kg/m2	09SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	09SEP2020 (1)	11:46

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	01OCT2020 (23)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: Pregnancy	1	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Withdrawn	VACCINATION	30OCT2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1232 12321213, a 23-year-old black or African American female with a pertinent obstetrical history of 2 previous pregnancies resulting in 2 live births, received Dose 1 on 09 Sep 2020. The subject's pregnancy was confirmed on 01 Oct 2020, 22 days after receiving Dose 1. On 01 Oct 2020 (Day 23), at Visit 2, the subject's urine pregnancy test was positive. The information available at the time of this report was that the father did not take any medications during the mother's pregnancy. The pregnancy was considered an important medical event by the investigator. The subject was discontinued from the study intervention on 30 Oct 2020 because of the pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the pregnancy was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1988	32	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	95.45 kg	34.9 kg/m2	01OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01OCT2020 (1)	12:36

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	Exposure During Pregnancy	22OCT2020 (22)	15:19	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: pregnancy	1	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01OCT2020	
Withdrawn	VACCINATION	22OCT2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1232 12321293, a 32-year-old black or African American female with no reported medical history, received Dose 1 on 01 Oct 2020. The subject reported an exposure during pregnancy on 22 Oct 2020 (Day 22). On 22 Oct 2020 (Day 22), during Visit 2, the subject's pregnancy test was positive. The subject's first day of her last menstrual period was on an unspecified date in Sep 2020. The gestational age at the time of initial exposure was unknown. The subject reported no previous pregnancies. It was reported that the subject did not smoke, drink alcohol, or use illicit drugs during this pregnancy. The subject was discontinued from the study intervention on 22 Oct 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the exposure during pregnancy was related to the study intervention, concomitant medications or clinical trial procedures.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	76.5 kg	27.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
chronic low back pain	Back pain	2013	Present
Bariatric surgery	Metabolic surgery	05JAN2013	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	12:25

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Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Exposure during pregnancy	Exposure during pregnancy	10SEP2020 (23)		14OCT2020 (57)		35
2	PREG	Retained products of conception	RETAINED PRODUCTS OF CONCEPTION	14OCT2020 (57)		14OCT2020 (57)		1
3	REPRO	Vaginal haemorrhage	Vaginal bleeding	05OCT2020 (48)		14OCT2020 (57)		10

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		P	N	Resolved (14OCT2020)	NOT RELATED/OTHER: Pregnancy	1	23	Y
2	3	TC	Y	Resolved (14OCT2020)	NOT RELATED/OTHER: Vaginal bleeding	1	57	N
3	1	TC	N	Resolved (14OCT2020)	NOT RELATED/OTHER: threat of abortion	1	48	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	10SEP2020	PREGNANCY
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1241 12411279, a 35-year-old black or African American female with a pertinent medical history of 3 prior pregnancies complicated by gestational hypertension with the first and ectopic pregnancy with the second, received Dose 1 on 19 Aug 2020. The subject reported an exposure during pregnancy on 10 Sep 2020, 22 days after receiving Dose 1. Concomitant medication reported 2 weeks prior to the onset of exposure during pregnancy included ketoprofen (from 09 Sep 2020 to 10 Sep 2020) for back pain. The date of the subject's last menstrual period was 09 Aug 2020, and the estimated date of conception was 22 Aug 2020. On 10 Sep 2020 (Day 23), at Visit 2, the subject's urine and serum (β-human chorionic gonadotropin) pregnancy tests were positive. The gestational age at time of initial exposure was first trimester. The subject denied smoking, alcohol use, or use of illicit drugs during the pregnancy. It was reported that during the pregnancy, the subject's partner drank alcohol (socially). The subject was discontinued from the study intervention on 10 Sep 2020 because of the exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. On 05 Oct 2020 (Day 48), the subject experienced vaginal hemorrhage. On 07 Oct 2020 (Day 50), the subject received scopolamine butylbromide and metamizole sodium both for colic. On 14 Oct 2020 (Day 57), the serious adverse event of retained products of conception was reported resulting in hospitalization. The investigator considered retained products of conception as an important medical event. The subject presented to the emergency room and a transvaginal ultrasonography showed a gestational age of approximately 7 weeks and 5 days. The subject underwent uterine curettage and had a spontaneous abortion. The procedure was performed without intercurrences. The subject received metamizole sodium, ferrous sulfate, and general anesthesia during this procedure. On 14 Oct 2020 (Day 57), the retained products of conception and vaginal hemorrhage were considered resolved. On 16 Oct 2020 (Day 59), the subject was discharged from the hospital. In the opinion of the investigator, there was no reasonable possibility that the exposure during pregnancy was related to the study intervention, concomitant medications, or clinical trial procedures.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	34	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	81.3 kg	27.2 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergic rhinitis	Rhinitis allergic	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	18:21

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Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INJ&P	Maternal exposure during pregnancy	Maternal exposure during pregnancy	09OCT2020 (24)		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			P	N	Yes	NOT RELATED/OTHER: Pregnancy	1	24	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Withdrawn	VACCINATION	09OCT2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1241 12411766, a 34-year-old white female with a pertinent medical history of 1 previous pregnancy and miscarriage in Aug 2019, received Dose 1 on 16 Sep 2020. The subject reported maternal exposure during pregnancy on 09 Oct 2020, 23 days after receiving Dose 1. Concomitant medication reported 2 weeks prior to the onset of the maternal exposure during pregnancy included folic acid (since 04 Oct 2020) as a vitamin supplement. On 09 Oct 2020 (Day 24), at Visit 2, the subject's urine and serum pregnancy tests were positive. The β-human chorionic gonadotropin was 9157.8 MiU/mL (normal range: 5.0-25.0 MiU/mL). The date of the subject's last menstrual period was 03 Sep 2020 and the estimated date of conception was 17 Sep 2020 (Day 2). The gestational age at the time of initial exposure was first trimester. On 21 Oct 2020 (Day 36), an obstetric ultrasonography dated the pregnancy at 6 weeks and 5 days. The subject denied smoking, alcohol use, or use of illicit drugs during this pregnancy. The subject's partner had no relevant history and did not take any drugs (over the counter or medical prescription) during this pregnancy. It was reported the subject received vitamin D during this pregnancy (since 21 Oct 2020). The subject was discontinued from the study intervention on 09 Oct 2020 because of the maternal exposure during pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the maternal exposure during pregnancy was related to the study intervention, concomitant medications, or clinical trial procedures.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	62 kg	21 kg/m2	28SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hysterectomy	Hysterectomy	1998	Past
Asthma	Asthma	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28SEP2020 (1)	10:30

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Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Urticaria	Intermittent urticaria generalised.	07OCT2020 (10)		02NOV2020 (36)	
2	SKIN	Urticaria	urticaria generalized	29SEP2020 (2)	00:01	02OCT2020 (5)	18:15

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	27	2	TC/P	N	Resolved (02NOV2020)	Study Treatment	1	10	Y
2	4	3	TC	N	Resolved (02OCT2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28SEP2020	
Withdrawn	VACCINATION	19OCT2020	ADVERSE EVENT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1246 12461025, a 45-year-old white female with pertinent medical history of asthma (in 2015), received Dose 1 on 28 Sep 2020. The subject reported urticaria on 2 occasions after receiving Dose 1. The subject had an initial episode on 29 Sep 2020 (Day 2) lasting until 02 Oct 2020 (Day 5). The second episode took place on 07 Oct 2020 (Day 10) lasting until 02 Nov 2020 (Day 36). The subject was discontinued from the study intervention on 19 Oct 2020 because of the additional episode of urticaria and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was a reasonable possibility that the urticaria was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2001	19	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183 cm	88 kg	26.3 kg/m2	30SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30SEP2020 (1)	11:24
2	Placebo	21OCT2020 (22)	10:17

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	INJ&P	Flail chest	Flail Chest	30OCT2020 (31)		13NOV2020 (45)		15	3	TC/TCN/W
2	INJ&P	Road traffic accident	Motorcyle accident	30OCT2020 (31)		30OCT2020 (31)		1	4	N

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (13NOV2020)	NOT RELATED/OTHER: Flail chest secondary to motorcycle accident	2	10	Y
2	N	Resolved (30OCT2020)	NOT RELATED/OTHER: Motorcycle accident	2	10	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30SEP2020	
Withdrawn	VACCINATION	30OCT2020	WITHDRAWAL BY SUBJECT
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1247 12471121, a 19-year-old white female with no reported medical history, received Dose 1 on 30 Sep 2020 and Dose 2 on 21 Oct 2020 (Day 22). The subject had a flail chest on 30 Oct 2020, 9 days after receiving Dose 2. Concomitant medications reported within 2 weeks prior to the onset of the flail chest included paracetamol (from 21 Oct 2020 to 29 Oct 2020) and diclofenac potassium (from 24 Oct 2020 to 29 Oct 2020), both for fever related to expected reactogenicity. On 30 Oct 2020 (Day 31), the subject had a motorcycle accident resulting in a flail chest. The subject went to the emergency room and was subsequently hospitalized. On 31 Oct 2020 (Day 32), the subject underwent surgery for rib fractures, which included open reduction and internal fixation (with plates and screws). On 01 Nov 2020 (Day 33), the subject was discharged from the hospital on tramadol 50 mg 3 times a day and paracetamol 1 g 4 times a day, and was advised strict rest for 8 to 12 weeks. On 13 Nov 2020 (Day 45), the subject recovered from the flail chest. The subject requested withdrawal from the study on 30 Oct 2020. In the opinion of the investigator, there was no reasonable possibility that the flail chest was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was secondary to a motor vehicle accident. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.9 cm	43 kg	16.4 kg/m2	30SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1991	Present
Post Menopausal	Postmenopause	2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30SEP2020 (1)	13:39

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Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Cerebellar infarction	Chronic cerebelar infarcts	23OCT2020 (24)	11:34	ONGOING			1	N	N
2	NERV	Cerebral atrophy	Cerebral atrophy	23OCT2020 (24)	11:34	ONGOING			1	N	N
3	NERV	Cerebral infarction	Left Middle Cerebral Artery Infarct	21OCT2020 (22)		ONGOING			3	TC/TCN/P	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: CT finding	1	24	N
2	Yes	NOT RELATED/OTHER: CT Findings	1	24	N
3	Yes	NOT RELATED/OTHER: Pt.68 years old; and 50 pack year history of smoking as risk factors for event.	1	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30SEP2020	
Withdrawn	VACCINATION	21OCT2020	ADVERSE EVENT
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1247 12471135, a 69-year-old white female with no pertinent medical history, received Dose 1 on 30 Sep 2020. The subject had a history of smoking since 1962 (50 packs a year). The subject was diagnosed with cerebral infarction on 21 Oct 2020, 21 days after receiving Dose 1. Concomitant medications reported within 2 weeks prior to the onset of cerebral infarction included salbutamol and budesonide (both since 1991) for asthma; and ibuprofen, paracetamol, and tramadol (all since 28 May 2020) for chronic left arm pain. On 21 Oct 2020 (Day 22), the subject had slurred speech and presented to the emergency department. The clinical examination revealed expressive aphasia and a left facial droop. That same day (Day22), the vital signs showed a blood pressure of 134/57 mmHg, heart rate of 119 beats per minutes, body temperature of 35.7C°, respiratory rate of 20 breaths per minute, and oxygen saturation of 96% on room air. An electrocardiogram showed p-pulmonale, which was not clinically significant. Laboratory test results showed a high urea level of 8.4 mmol/L, platelet count of 290 × 109/L (normal ranges [NR] not reported), and glucose of 5.5 (unit and NR not reported) with all other laboratory test results within normal limits. A computerized tomogram on 23 Oct 2020 (Day 24) revealed acute infarct in the middle cerebral artery distribution on the left side, along with chronic cerebellar infarcts and cerebral atrophy. The subject was diagnosed with cerebral infarction (left middle cerebral artery infarct) with an onset date of 21 Oct 2020 (Day 22) and was subsequently hospitalized. The subject was treated with simvastatin 20 mg and aspirin 150 mg, both orally once daily since 21 Oct 2020 (Day 22). She also received physiotherapy, occupational therapy, and speech therapy. The subject's clinical condition improved and speech was also improving. The subject was discharged on 28 Oct 2020 (Day 29) and was advised to follow-up with speech therapy. The cerebral atrophy and chronic cerebellar infarction were ongoing at the time of the last available report. The subject was discontinued from the study intervention on 21 Oct 2020 because of the cerebral infarction that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the cerebral infarction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather related to the age of the subject and history of smoking. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the cerebral infarction was most likely coincidental and associated with underlying clinical conditions.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1994	26	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174.5 cm	69.4 kg	22.8 kg/m2	20SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

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Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Syncope	vasovagal syncope	20SEP2020 (1)	13:54	20SEP2020 (1)	14:52	1	2
2	GASTR	Vomiting	Vomiting	20SEP2020 (1)	14:52	21SEP2020 (2)	14:53	2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	N	Resolved (20SEP2020)	NOT RELATED/OTHER: Study Procedure (phlebotomy)			Y
2	TCN	N	Resolved (21SEP2020)	NOT RELATED/OTHER: unknown			N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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FDA-CBER-2021-5683-1787657

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20SEP2020	
Withdrawn	VACCINATION	21SEP2020	ADVERSE EVENT
Withdrawn	FOLLOW-UP	21SEP2020	ADVERSE EVENT

Narrative Comment
Subject C4591001 1248 12481218, a 26-year-old white male with no reported medical history, reported syncope during the prevaccination blood sample collection on 20 Sep 2020 (Day 1), which resolved on the same day. On 20 Sep 2020 (Day 1), the subject also reported vomiting, which resolved on 21 Sep 2020 (Day 2). The subject was withdrawn from the study before study vaccination on 21 Sep 2020 because of the syncope. In the opinion of the investigator, there was no reasonable possibility that the syncope was related to the study intervention, but rather it was related to the study procedure (phlebotomy).

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FDA-CBER-2021-5683-1787658

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	21	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.6 cm	63.05 kg	23.8 kg/m2	12SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	2015	Present
Recurrent Miscarriage	Abortion spontaneous	2016	Past
Seasonal Allergies	Seasonal allergy	2017	Present
Benedryl Allergy	Drug hypersensitivity	2019	Present

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Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	12SEP2020 (1)	13:13

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Abdominal pain upper	stomach pain	15SEP2020 (4)	09:00	15SEP2020 (4)	14:00	1	2
2	SKIN	Alopecia	hair loss	OCT2020 ()		ONGOING			1
3	INV	Body temperature increased	elevated body temperature at 100.0F	13SEP2020 (2)	07:30	14SEP2020 (3)	04:00	2	1
4	INV	Body temperature increased	elevated body temperature at 100.0F	14SEP2020 (3)	10:00	15SEP2020 (4)		2	2
5	GENRL	Chills	intermittent chills	12SEP2020 (1)	22:00	25SEP2020 (14)		14	1
6	EYE	Eye irritation	left eye irritation	12SEP2020 (1)	16:00	14SEP2020 (3)		3	1
7	NERV	Headache	headache intermittent	15SEP2020 (4)		25SEP2020 (14)		11	2
8	INJ&P	Maternal exposure during pregnancy	Maternal Exposure During Pregnancy	12SEP2020 (1)	13:13	ONGOING			
9	GASTR	Nausea	Nausea	26SEP2020 (15)		ONGOING			1
10	EYE	Ocular hyperaemia	left eye redness	12SEP2020 (1)	16:00	14SEP2020 (3)		3	1
11	GENRL	Pyrexia	fever at 102.0F	14SEP2020 (3)	04:00	14SEP2020 (3)	08:00	1	2
12	INV	Weight decreased	weight loss	OCT2020 ()		ONGOING			1

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Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (15SEP2020)	NOT RELATED/OTHER: unknown etiology but due to gas	1	4	N
2	N	N	Yes	NOT RELATED/OTHER: pregnancy			N
3	N	N	Resolved (14SEP2020)	Study Treatment	1	2	N
4	TC	N	Resolved (15SEP2020)	Study Treatment	1	3	N
5	N	N	Resolved (25SEP2020)	Study Treatment	1	1	N
6	N	N	Resolved (14SEP2020)	NOT RELATED/OTHER: unknown etiology	1	1	N
7	TC	N	Resolved (25SEP2020)	Study Treatment	1	4	N
8	P	N	Yes	NOT RELATED/OTHER: pregnancy	1	1	Y
9	N	N	Yes	NOT RELATED/OTHER: Likely From Pregnancy	1	15	N
10	N	N	Resolved (14SEP2020)	NOT RELATED/OTHER: unknown etiology	1	1	N
11	TC	N	Resolved (14SEP2020)	Study Treatment	1	3	N
12	N	N	Yes	NOT RELATED/OTHER: pregnancy			N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12SEP2020	
Withdrawn	VACCINATION	07OCT2020	PREGNANCY
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1254 12541142, a 21-year-old white female with a pertinent obstetrical history of spontaneous abortion (in 2016), and 4 previous pregnancies that resulted in 2 spontaneous abortions in 2018 and 2019, 1 therapeutic abortion in 2018, and 1 live birth in May 2020, received Dose 1 on 12 Sep 2020. The subject was confirmed to have a positive pregnancy test on 02 Oct 2020 (Day 21). During Visit 1 on 11 Sep 2020 (Day -1), the subject had reported using contraceptives and her urine pregnancy test was negative. The first day of her last menstrual period was 12 Sep 2019. On 02 Oct 2020 (Day 21), the subject contacted the site to reschedule Visit 2 because of ongoing nausea, which started on 26 Sep 2020 (Day 15). That same day, she visited her personal physician for discomfort not specified and ongoing nausea. An evaluation including blood work was performed to evaluate her condition. The study coordinator suggested that she attend Visit 2 on 03 Oct 2020 (Day 22) for the study investigator to perform a physical examination. Although the subject agreed to attend Visit 2, she did not keep the appointment. Since the subject failed to attend Visit 2, the study site obtained medical records from her doctor's office on 07 Oct 2020 (Day 26). According to the medical records, the subject visited her doctor because of unprotected sex and vaginal spotting. The subject had a positive urine pregnancy test on 02 Oct 2020 (Day 21). On 03 Oct 2020 (Day 22), the subject returned to her doctor's office and had a transvaginal ultrasound scan, which showed 7 weeks and 2 days of pregnancy, with fetal cardiac activity noted. The subject had previously delivered a baby about 4 months before Visit 1. The estimated date of conception was considered as 29 Aug 2020 (Day -14). The subject did not smoke, drink alcohol, or use illicit drugs before the positive pregnancy test. The investigator considered the pregnancy to be an important medical event. The subject was discontinued from the study intervention on 07 Oct 2020 because of the pregnancy and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the pregnancy was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	91.5 kg	28.9 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	05JAN2011	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	05JUN2011	Present
Chronic Deep Vein Thrombosis of bilateral legs	Deep vein thrombosis	06JUL2011	Present
Factor V Leiden Mutation, heterozygous	Factor V Leiden mutation	06JUL2011	Present
Hyperlipidemia	Hyperlipidaemia	06JUL2011	Present
Diabetes Mellitus 2	Type 2 diabetes mellitus	06JUL2011	Present
Spinal stenosis of lumbar spine with neurogenic claudication	Lumbar spinal stenosis	28JUL2011	Present
Erectile dysfunction	Erectile dysfunction	21NOV2016	Present
Peripheral neuropathy	Neuropathy peripheral	21NOV2016	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Actinic keratosis	Actinic keratosis	20SEP2017	Present
Insomnia	Insomnia	20SEP2017	Present
Anxiety	Anxiety	18DEC2017	Present
Lumbar radiculopathy	Lumbar radiculopathy	11MAY2018	Present
Arthritis of bilateral hips	Arthritis	27FEB2019	Present
Osteoarthritis of right knee	Osteoarthritis	27FEB2019	Present
Chronic pain syndrome	Pain	07MAR2019	Present
Allergy to Tramadol	Drug hypersensitivity	30MAY2019	Present
Genital Herpes Simplex	Genital herpes simplex	03APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	11:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Pulmonary embolism	Pulmonary embolism	23SEP2020 (21)		ONGOING		

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Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/P	Y	Yes	NOT RELATED/OTHER: Factor V Leiden Mutation	1	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Withdrawn	VACCINATION	02NOV2020	ADVERSE EVENT
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1270 12701057, a 65-year-old white male with a pertinent medical history of deep vein thrombosis (DVT; bilateral legs), factor V Leiden mutation, hyperlipidemia, and type 2 diabetes mellitus (all since 06 Jul 2011), received Dose 1 on 03 Sep 2020. The subject was diagnosed with a pulmonary embolism on 23 Sep 2020, 20 days after receiving Dose 1. Concomitant medications reported within 2 weeks before the pulmonary embolism included metformin (since 25 Dec 2015) for type 2 diabetes mellitus, acyclovir (since 03 Apr 2020) for genital herpes simplex, famotidine (since 03 Apr 2020) for gastroesophageal reflux disease, ciclesonide (since 20 Aug 2020) for asthma, albuterol (since 30 Mar 2015) for asthma, lovastatin (since 30 Aug 2019) for hyperlipidemia, and dabigatran etexilate mesylate (from 25 Jul 2018 to 25 Sep 2020) for recurrent DVT. On 24 Sep 2020 (Day 22), the subject presented to the emergency department (ED) because of shortness of breath and cough starting on 04 Sep 2020 (Day 2) and chest tightness since 23 Sep 2020 (Day 21). The subject thought these symptoms were related to the smoke in the air and his inhalers were not helping. The SARS-CoV-2 test result was negative and troponin I was <0.02 ng/mL (normal range [NR]: 0.00 - 0.04 ng/mL). The subject received albuterol inhaler once, acetylsalicylic acid 325 mg once orally, and normal saline bolus once intravenously. On 24 Sep 2020 (Day 22), the subject went home against medical advice as he was admitted to the COVID-19 area of the emergency room. After he was back home, the symptoms improved but were still present; therefore, the subject went back to the ED on 25 Sep 2020 (Day 23). A computed tomography angiogram of chest performed on 25 Sep 2020 (Day 23) was positive for acute pulmonary embolism, which was reported to be life-threatening and medically significant. On 25 Sep 2020 (Day 23), troponin I was <0.02 ng/mL, prothrombin time (PT) was 15.5 seconds (NR: 11.7 - 14.3 seconds), and international normalized ratio (INR) was 1.3 (NR: 2.0 - 3.0). The subject discontinued treatment with dabigatran etexilate mesylate and received enoxaparin 80 mg subcutaneously. The subject was discharged home on the same day (Day 23) in stable condition with a prescription for enoxaparin and warfarin and was referred to hematology/oncology. The subject continued to experience shortness of breath since 26 Sep 2020 (Day 24) and chest tightness since 27 Sep 2020 (Day 25). The subject was advised to postpone travel for 6 weeks, continue anticoagulant therapy with enoxaparin and warfarin, and monitor PT/INR levels. On 29 Sep 2020 (Day 27), the PT was 21.7 seconds and the INR level was 2.0. On 01 Oct 2020 (Day 29), the PT was 23.6 seconds and the INR level was in therapeutic range at 2.2, and the subject was advised to discontinue treatment with enoxaparin and continue warfarin. The subject continued to have shortness of breath, fatigue, and mild cough on 02 Oct 2020 (Day 30). On 05 Oct 2020 (Day 33), a repeat SARS-CoV-2 NAAT result was negative and PT was 33.2 seconds and INR was above therapeutic range at 3.3. On 09 Oct 2020 (Day 37), the PT was 32.9 seconds and the INR was 3.3, and warfarin doses were titrated. On 15 Oct 2020 (Day 43), the INR was therapeutic (value not reported), and a trial weekly dose of warfarin was recommended. On 21 Oct 2020 (Day 49), the PT was 22.6 seconds and the INR was in therapeutic range at 2.1. On 28 Oct 2020 (Day 56), the PT was 19.9 seconds and the INR was sub-therapeutic at 1.8, and the subject was instructed to increase the dose of warfarin and recheck the INR in 1 week. The subject was discontinued from the study intervention on 02 Nov 2020 because of the pulmonary embolism that was ongoing at the time of the last available report and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the pulmonary embolism was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to factor V Leiden mutation. Pfizer concurred with the investigator's assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1990	29	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	77.9 kg	27.9 kg/m2	25SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	16:20

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Exposure during pregnancy	EXPOSURE DURING PREGNANCY	05SEP2020 (-20)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: not applicable			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Withdrawn	VACCINATION	15OCT2020	PREGNANCY
Withdrawn	FOLLOW-UP	11NOV2020	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject C4591001 4444 44441979, a 29-year-old white female with an obstetrical history of 1 previous pregnancy that resulted in a live birth via a cesarean section because of polyhydramnios, received Dose 1 on 25 Sep 2020 (Day 1). On 09 Oct 2020 (Day 15), the subject informed the site that she had a positive urine pregnancy test that day. The first day of her last menstrual period was 05 Sep 2020 (Day -20) and the estimated date of conception was 05 Sep 2020 (Day -20). The gestational at the time of initial exposure was 1st trimester. The subject smoked; however, she did not drink alcohol or use illicit drugs before the positive pregnancy test. The father smoked; however, he did not drink alcohol or use illicit drugs. The subject was discontinued from the study intervention on 15 Oct 2020 because of the pregnancy and decided to withdraw from the study on 11 Nov 2020. In the opinion of the investigator, there was no reasonable possibility that the pregnancy was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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FDA-CBER-2021-5683-1787669

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	70 kg	24.1 kg/m2	12JUN2020 (-12)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Wears Glasses	Corrective lens user	1982	Present
Deviated Septum - Nasal Surgery	Nasal septal operation	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24JUN2020 (1)	11:32
2	BNT162b2	15JUL2020 (22)	09:46

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FDA-CBER-2021-5683-1787670

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Neuritis	neuritis right arm	29JUL2020 (36)		ONGOING		
2	MUSC	Pain in extremity	right arm pain	29JUL2020 (36)	09:40	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Yes	NOT RELATED/OTHER: related to study blood draw	2	15	Y
2	2	N	N	Yes	NOT RELATED/OTHER: unknown	2	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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FDA-CBER-2021-5683-1787671

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12JUN2020	
Completed	VACCINATION	19AUG2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	71.82 kg	22 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	2000	Present
Osteoarthritis	Osteoarthritis	2000	Present
Interstitial Lung Disease	Interstitial lung disease	2017	Present
Seasonal Allergies	Seasonal allergy	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	30JUL2020 (1)	13:55
2	Placebo	20AUG2020 (22)	13:04

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Interstitial lung disease	worsening of interstitial lung disease	17OCT2020 (80)		ONGOING		
2	MUSC	Scleroderma	possible scleroderma	20OCT2020 (83)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN	Y	Yes	NOT RELATED/OTHER: worsening of interstitial lung disease	2	59	Y
2	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: possible scleroderma	2	62	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	21SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	86.82 kg	26.6 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	1959	Past
appendicitis	Appendicitis	1959	Past
high blood pressure	Hypertension	2009	Present
gastrointestinal reflux disorder	Duodenogastric reflux	2013	Present
benign prostatic hypertrophy	Benign prostatic hyperplasia	2017	Present
environmental allergies - hives	Urticaria	2019	Present
right eye cataract	Cataract	FEB2019	Past
right eye cataract removal	Cataract operation	FEB2019	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05AUG2020 (1)	15:19
2	Placebo	26AUG2020 (22)	14:57

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Small intestinal obstruction	small bowel obstruction	08AUG2020 (4)	00:17	10AUG2020 (6)	00:13	3	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (10AUG2020)	NOT RELATED/OTHER: SAE - unplanned bowel obstruction	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	23SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	54	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	137.55 kg	48.8 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HIGH BLOOD PRESSURE	Hypertension	1980	Present
DEPRESSION	Depression	1985	Present
MORPHINE ALLERGY	Drug hypersensitivity	1985	Present
ANXIETY	Anxiety	2004	Present
HYSTERECTOMY	Hysterectomy	2008	Past
UTERINE FIBROIDS	Uterine leiomyoma	2008	Past
MENOPAUSE	Menopause	2017	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	12:04
2	BNT162b2	04SEP2020 (23)	10:58

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Non-cardiac chest pain	INTERMITTENT NON CARDIAC CHEST PAIN	09SEP2020 (28)		17SEP2020 (36)		9

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	Y	Resolved (17SEP2020)	NOT RELATED/OTHER: IDIOPATHIC	2	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	64.55 kg	26.8 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
controlled squamous cell carcinoma skin on chin	Squamous cell carcinoma of skin	1993	Present
MENOPAUSE	Menopause	2002	Present
HIGH BLOOD PRESSURE	Hypertension	2004	Present
LEFT BREAST CANCER	Breast cancer	2005	Past
LEFT BREAST LUMPECTOMY	Breast conserving surgery	2010	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	09:34
2	Placebo	02SEP2020 (20)	15:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Breast cancer	LEFT BREAST CANCER	04SEP2020 (22)		ONGOING			1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Yes	NOT RELATED/OTHER: PRE-EXISTING OCCULT MALIGNANCY	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	60	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183.64 cm	93.91 kg	27.8 kg/m2	19OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
VASECTOMY	Vasectomy	2005	Past
CERVICAL FUSION	Spinal fusion surgery	2013	Past
RIGHT INGUINAL HERNIA REPAIR	Inguinal hernia repair	2016	Past
OSTEOARTHRITIS	Osteoarthritis	2017	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2018	Present
HIGH CHOLESTEROL	Blood cholesterol increased	JAN2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19OCT2020 (1)	08:47

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	RESP	Acute respiratory failure	Acute Respiratory Failure	08NOV2020 (21)	00:43	ONGOING			4	N	Y
2	CARD	Cardiac arrest	CARDIAC ARREST	08NOV2020 (21)	00:43	08NOV2020 (21)		1	4	TC	Y
3	INJ&P	Overdose	Overdose	08NOV2020 (21)	00:43	08NOV2020 (21)		1	4	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: unknown	1	21	Y
2	Resolved (08NOV2020)	NOT RELATED/OTHER: possible intentional overdose, or. poor choice of alcohol and drug abuse.	1	21	Y
3	Resolved (08NOV2020)	NOT RELATED/OTHER: unknown	1	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19OCT2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.01 cm	60.55 kg	21.7 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Ehlers-Danlos Syndrome	Ehlers-Danlos syndrome	1966	Present
Postural Orthostatic Tachycardia Syndrome	Postural orthostatic tachycardia syndrome	1966	Present
Environmental Allergies	Hypersensitivity	1969	Present
Recurrent Urinary Tract Infection	Urinary tract infection	1974	Present
Migraines with Aura	Migraine with aura	1979	Present
Recurrent Sinusitis	Sinusitis	1980	Past
Asthma (Moderate)	Asthma	1985	Present
Complete Hysterectomy	Hysterectomy	1989	Past
Postmenopausal	Postmenopause	1989	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Post Partum Hemorrhage	Postpartum haemorrhage	1989	Past
Premarin Allergy (Hives)	Urticaria	1989	Present
Attention Deficit Hyperactivity Disorder	Attention deficit hyperactivity disorder	01FEB1989	Present
Macrodantin Allergy (Hives)	Urticaria	1990	Present
Restless Leg Syndrome	Restless legs syndrome	2000	Present
History of Recurrent Actinic Keratosis	Actinic keratosis	06SEP2011	Present
Basal Cell Carcinoma (Forehead)	Basal cell carcinoma	11SEP2011	Past
Rosacea (mild)	Rosacea	12SEP2011	Present
Chronic Fatigue Syndrome	Chronic fatigue syndrome	14AUG2012	Present
Insomnia	Insomnia	13SEP2013	Present
Mild Anxiety	Anxiety	19MAY2014	Present
Lumbar Disc Degeneration	Intervertebral disc degeneration	14AUG2014	Present
Tinnitus Left Ear	Tinnitus	12MAR2015	Present
Bilateral Eye Cataracts	Cataract	20OCT2016	Past
Recurrent Muscle Spasms (Whole Body)	Muscle spasms	10MAR2017	Present
Gastrointestinal Bleed	Gastrointestinal haemorrhage	27NOV2017	Past
Urethral Sling	Urinary bladder suspension	2018	Present
Osteoporosis	Osteoporosis	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	13:34
2	BNT162b2	15SEP2020 (23)	15:51

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Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	ATRIAL FIBRILLATION INTERMITTENT	06OCT2020 (44)		12OCT2020 (50)		7	2
2	NERV	Headache	Headache	24AUG2020 (1)	14:30	25AUG2020 (2)	07:00	2	2
3	INFEC	Urinary tract infection	URINARY TRACT INFECTION	03OCT2020 (41)		12OCT2020 (50)		10	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (12OCT2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	22	Y
2	TC	N	Resolved (25AUG2020)	Study Treatment	1	1	N
3	TC	N	Resolved (12OCT2020)	NOT RELATED/OTHER: BACTERIAL INFECTION	2	19	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	02OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187 cm	91.4 kg	26.1 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergy	Seasonal allergy	1987	Present
Asthma	Asthma	1990	Present
Vasectomy	Vasectomy	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	15:11
2	Placebo	17SEP2020 (23)	14:33

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Chronic myeloid leukaemia	chronic myelogenous leukemia	24SEP2020 (30)		ONGOING			4
2	BLOOD	Leukocytosis	leukocytosis	24SEP2020 (30)		19OCT2020 (55)		26	3
3	BLOOD	Thrombocytosis	thrombocytosis	24SEP2020 (30)		26OCT2020 (62)		33	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/OTHER: Genetic change in stem cells	2	8	Y
2	N	N	Resolved (19OCT2020)	NOT RELATED/OTHER: Chronic myelogenous leukemia	2	8	N
3	N	N	Resolved (26OCT2020)	NOT RELATED/OTHER: Chronic myelogenous leukemia	2	8	N

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Dasatinib	DASATINIB	06OCT2020	ONGOING	ORAL

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	92 kg	28.4 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to food - shellfish	Food allergy	1952	Present
drug allergy Penicillin	Drug hypersensitivity	1958	Present
drug allergy sulfa	Drug hypersensitivity	1958	Present
Hepatitis B	Hepatitis B	1970	Past
Tobacco use disorder, continuous use	Tobacco abuse	1975	Present
Hypertension	Hypertension	1980	Present
Reflux esophagitis	Gastrooesophageal reflux disease	1989	Present
Fundoplication	Oesophagogastric fundoplasty	1989	Past
Asthma	Asthma	1990	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hepatitis C	Hepatitis C	1999	Past
COPD	Chronic obstructive pulmonary disease	2000	Present
Cardiac surgery	Cardiac operation	2006	Past
Coronary artery disease	Coronary artery disease	2006	Present
Iodine allergy	Iodine allergy	2006	Present
Enlarged prostate (benign)	Benign prostatic hyperplasia	25APR2011	Present
Hypercholesterolemia	Hypercholesterolaemia	25NOV2011	Present
Depression	Depression	2016	Present
Post-traumatic stress disorder	Post-traumatic stress disorder	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15OCT2020 (1)	14:40

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	atrial fibrillation	25OCT2020 (11)	11:30	26OCT2020 (12)		2	3

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Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (26OCT2020)	NOT RELATED/OTHER: history of coronary artery disease	1	11	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15OCT2020	
Withdrawn	VACCINATION	05NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	62	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	109.55 kg	38.9 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Thimerosal allergy	Drug hypersensitivity	1974	Present
High cholesterol	Blood cholesterol increased	2019	Present
Elevated PSA	Prostatic specific antigen increased	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	14:32
2	Placebo	24SEP2020 (22)	10:57

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Prostate cancer	Prostate cancer	30SEP2020 (28)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: Unknown	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flucelvax influenza prophylaxis intramuscular vaccine 0.5 ml once	INFLUENZA VACCINE INACT SAG 3V	19OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	92.09 kg	30.4 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	1980	Present
Diabetes type II	Type 2 diabetes mellitus	2000	Present
High cholesterol	Blood cholesterol increased	2014	Present
Coronary artery disease	Coronary artery disease	2015	Present
Sebaceous cyst of scalp	Dermal cyst	SEP2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14OCT2020 (1)	11:44
2	Placebo	05NOV2020 (23)	15:06

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Cellulitis	CELLULITIS UPPER BACK	26OCT2020 (13)		02NOV2020 (20)		8	3
2	INFEC	Sepsis	SEPSIS	26OCT2020 (13)		02NOV2020 (20)		8	3
3	INFEC	Subcutaneous abscess	SCALP ABCESS	26OCT2020 (13)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (02NOV2020)	NOT RELATED/OTHER: SCALP ABCESS	1	13	Y
2	TC	Y	Resolved (02NOV2020)	NOT RELATED/OTHER: SCALP ABCESS	1	13	Y
3	TC/TCN	N	Yes	NOT RELATED/OTHER: HISTORY SCALP CYST	1	13	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14OCT2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	110.55 kg	41.7 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MTHFR GENE MUTATION	Methylenetetrahydrofolate reductase gene mutation	(b) (6) 1957	Present
ENVIRONMENTAL ALLERGIES	Hypersensitivity	1958	Present
LACTOSE INTOLERANCE	Lactose intolerance	1970	Present
ASPIRIN INTOLERANCE	Drug intolerance	1986	Present
MORPHINE INTOLERANCE	Drug intolerance	1986	Present
HYSTERECTOMY	Hysterectomy	1986	Past
GLUTEN INTOLERANCE	Gluten sensitivity	2003	Present
ANXIETY	Anxiety	JUN2011	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DEPRESSION	Depression	JUN2011	Present
HYPOTHYROIDISM	Hypothyroidism	JUN2011	Present
MILD ASTHMA	Asthma	2018	Present
OSTEOARTHRITIS (GENERALIZED)	Osteoarthritis	JUN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	13:44
2	Placebo	22SEP2020 (23)	16:22

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	REPRO	Breast mass	right breast lump	02SEP2020 (3)		ONGOING	
2	NEOPL	Intraductal proliferative breast lesion	Right Breast Ductal Carcinoma In Situ	02SEP2020 (3)		ONGOING	

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Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		1	N	N	Yes	NOT RELATED/OTHER: cancer	1	3	N
2		1	N	Y	Yes	NOT RELATED/OTHER: spontaneous onset	1	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	75.82 kg	28.6 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Postmenopausal	Postmenopause	1994	Present
Dilation and Curettage	Uterine dilation and curettage	1998	Past
Uterine Bleeding	Uterine haemorrhage	1998	Past
Facelift	Face lift	2001	Past
Insomnia	Insomnia	2015	Present
Overactive Bladder	Hypertonic bladder	2018	Present
Shingles	Herpes zoster	01APR2020	Past
Post Herpetic Neuralgia	Post herpetic neuralgia	10APR2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13AUG2020 (1)	16:47
2	Placebo	31AUG2020 (19)	14:13

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Appendicitis perforated	Perforated Appendicitis	12SEP2020 (31)	08:00	15SEP2020 (34)		4	3
2	INFEC	Peritonitis	Feculant Peritonitis	14SEP2020 (33)		18SEP2020 (37)		5	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (15SEP2020)	NOT RELATED/OTHER: Appendicitis	2	13	Y
2	TC/TCN	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: Perforated Appendicitis	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	01OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	57.6 kg	23.4 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RIGHT RENAL STENT INSERTION	Renal surgery	FEB2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05AUG2020 (1)	10:40
2	BNT162b2	26AUG2020 (22)	15:05

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Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Vascular stent occlusion	OBSTRUCTED RENAL STENT (ARTERY)	01SEP2020 (28)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: RENAL STENT	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174.9 cm	72.2 kg	23.6 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
LEFT KNEE OSTEOARTHRITIS	Osteoarthritis	1990	Past
RIGHT KNEE OSTEOARTHRITIS	Osteoarthritis	1990	Past
LEFT KNEE REPLACEMENT	Knee arthroplasty	2000	Past
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2005	Present
HIATAL HERNIA	Hiatus hernia	2005	Present
RIGHT KNEE REPLACEMENT	Knee arthroplasty	2009	Past
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2014	Present
HYPERTENSION	Hypertension	2015	Present
INGUINAL HERNIA	Inguinal hernia	2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SMALL BOWEL PERFORATION	Small intestinal perforation	2016	Past
SMALL BOWEL RESECTION	Small intestinal resection	2016	Past
INGUINAL HERNIA REPAIR	Inguinal hernia repair	2017	Past
CONSTIPATION	Constipation	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	12:35
2	BNT162b2	07OCT2020 (56)	15:10

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	GASTR	Abdominal adhesions	abdominal adhesions	29AUG2020 (17)		30AUG2020 (18)		2	3	TC
2	RENAL	Acute kidney injury	acute renal failure	29AUG2020 (17)		16SEP2020 (35)		19	3	N
3	RESP	Acute respiratory failure	acute hypoxic respiratory failure	30AUG2020 (18)		11SEP2020 (30)		13	3	N
4	BLOOD	Anaemia	anemia	30AUG2020 (18)		16SEP2020 (35)		18	3	N
5	CARD	Cardiac failure congestive	CONGESTIVE HEART FAILURE	30AUG2020 (18)		16SEP2020 (35)		18	3	N
6	METAB	Hypokalaemia	hypokalemia	30AUG2020 (18)		16SEP2020 (35)		18	3	N

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Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
7	METAB	Hyponatraemia	HYPONATREMIA	29AUG2020 (17)		07SEP2020 (26)		10	2	TC
8	CARD	Left ventricular hypertrophy	MILD CONCENTRIC LEFT VENTRICULAR HYPERTROPHY	16SEP2020 (35)		ONGOING			1	N
9	BLOOD	Leukopenia	LEUKOPENIA	29AUG2020 (17)		07SEP2020 (26)		10	2	TCN
10	PSYCH	Mental status changes	altered mental status	29AUG2020 (17)		16SEP2020 (35)		19	3	N
11	RESP	Pneumonia aspiration	ASPIRATION PNEUMONIA	30AUG2020 (18)		16SEP2020 (35)		18	2	TCN
12	INFEC	Sepsis	sepsis	29AUG2020 (17)		16SEP2020 (35)		19	3	N
13	GASTR	Small intestinal obstruction	SMALL BOWEL OBSTRUCTION	29AUG2020 (17)		30AUG2020 (18)		2	2	TCN

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (30AUG2020)	NOT RELATED/OTHER: PREVIOUS SURGERY	1	17	Y
2	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	17	N
3	Y	Resolved (11SEP2020)	NOT RELATED/OTHER: prior surgery	1	18	Y
4	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	18	N
5	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	18	N
6	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	18	N
7	N	Resolved (07SEP2020)	NOT RELATED/OTHER: BOWEL OBSTRUCTION	1	17	N
8	N	Yes	NOT RELATED/OTHER: UNKNOWN	1	35	N
9	N	Resolved (07SEP2020)	NOT RELATED/OTHER: BOWEL OBSTRUCTION	1	17	N
10	N	Resolved (16SEP2020)	NOT RELATED/CONCOMITANT NON-DRUG TREATMENT	1	17	N
11	Y	Resolved (16SEP2020)	NOT RELATED/OTHER: ADHESIONS	1	18	Y

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Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
12	N	Resolved (16SEP2020)	NOT RELATED/OTHER: prior surgery	1	17	N
13	Y	Resolved (30AUG2020)	NOT RELATED/OTHER: ADHESIONS	1	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	04NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.8 cm	77.1 kg	23.1 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ASTHMA	Asthma	1951	Present
VITILIGO	Vitiligo	1978	Present
CORONARY ARTERY DISEASE	Coronary artery disease	2005	Present
HYPOTHYROIDISM	Hypothyroidism	2016	Present
STENT CARDIAC INSERTION	Coronary arterial stent insertion	14FEB2016	Past
MYOCARDIAL INFARCTION	Myocardial infarction	14FEB2016	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	13:05
2	BNT162b2	30SEP2020 (21)	14:36

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Fatigue	FATIGUE	11SEP2020 (2)	07:00	11SEP2020 (2)	19:00	1	1
2	GENRL	Injection site pain	INJECTION SITE PAIN TO LEFT ARM	10SEP2020 (1)	07:00	11SEP2020 (2)	08:00	2	1
3	CARD	Myocardial infarction	MYOCARDIAL INFARCTION	08NOV2020 (60)		10NOV2020 (62)		3	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (11SEP2020)	Study Treatment	1	2	N
2	N	N	Resolved (11SEP2020)	Study Treatment	1	1	N
3	N	Y	Resolved (10NOV2020)	NOT RELATED/OTHER: MYOCARDIAL INFARCTION	2	40	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	47	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.01 cm	103.64 kg	37.1 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	JUN1985	Present
depression	Depression	JUN1987	Present
polycystic ovary syndrome	Polycystic ovaries	JUN1987	Present
hypothyroidism	Hypothyroidism	JUN1995	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	09:48
2	Placebo	02OCT2020 (22)	10:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	atrial fibrillation	09OCT2020 (29)	13:00	12OCT2020 (32)	10:00	4	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (12OCT2020)	NOT RELATED/OTHER: cardiac dysrhythmia	2	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	30OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2002	17	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.58 cm	60.18 kg	22.4 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	MAY2008	Present
asthma	Asthma	30JUN2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18SEP2020 (1)	10:00
2	BNT162b2	07OCT2020 (20)	09:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Chills	chills	18SEP2020 (1)	20:30	20SEP2020 (3)	11:30	3	2
2	INJ&P	Concussion	concussion	31OCT2020 (44)		ONGOING			2
3	INJ&P	Facial bones fracture	facial fractures	31OCT2020 (44)		ONGOING			3
4	GENRL	Pyrexia	fever	18SEP2020 (1)	20:30	20SEP2020 (3)	11:30	3	1
5	INJ&P	Road traffic accident	motor vehicle accident	31OCT2020 (44)		31OCT2020 (44)		1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (20SEP2020)	Study Treatment	1	1	N
2	N	N	Yes	NOT RELATED/OTHER: motor vehicle accident	2	25	N
3	TC	Y	Yes	NOT RELATED/OTHER: motor vehicle accident	2	25	Y
4	TC	N	Resolved (20SEP2020)	Study Treatment	1	1	N
5	N	N	Resolved (31OCT2020)	NOT RELATED/OTHER: motor vehicle accident	2	25	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1948	71	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	70.73 kg	28.5 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Iodine Allergy	Iodine allergy	1970	Present
Codeine Allergy	Drug hypersensitivity	1988	Present
Facial injuries	Face injury	1988	Past
Jaw surgery	Jaw operation	1988	Past
Nasal surgery	Nasal operation	1988	Past
Generalized Osteoarthritis	Osteoarthritis	1988	Present
Seasonal Allergic Rhinitis	Seasonal allergy	1988	Present
Vertigo	Vertigo	1988	Present
Asthma	Asthma	1990	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hysterectomy	Hysterectomy	1990	Past
Postmenopausal	Postmenopause	1990	Present
Uterine fibroids	Uterine leiomyoma	1990	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1994	Past
Hypothyroidism	Hypothyroidism	1994	Present
Hypertension	Hypertension	1999	Present
Hyperlipidemia	Hyperlipidaemia	2000	Present
Barrett's esophagus	Barrett's oesophagus	2004	Present
Nissen fundoplication - Surgery	Oesophagogastric fundoplasty	2004	Past
Acquired deformities of second toe of right foot	Foot deformity	2007	Present
Partial Left knee replacement	Knee arthroplasty	14MAY2007	Past
Sleep apnea	Sleep apnoea syndrome	2008	Present
Osteoporosis	Osteoporosis	JUN2008	Present
Vitamin D deficiency	Vitamin D deficiency	2009	Present
Lumbar radiculopathy	Lumbar radiculopathy	2010	Present
Fatigue	Fatigue	2012	Present
Prediabetes	Glucose tolerance impaired	2012	Past
Intermittent lower extremities edema	Oedema peripheral	2016	Present
Telangiectasias on lower extremities	Telangiectasia	2016	Present
Vitamin B12 deficiency	Vitamin B12 deficiency	2016	Present
Right trigger finger release	Tendon sheath incision	09DEC2016	Past
Right stenosing tenosynovitis	Tenosynovitis stenosans	09DEC2016	Past
Acute bronchitis	Bronchitis	15DEC2016	Past
Foot fracture	Foot fracture	2017	Past
Surgery - Foot fracture repair	Fracture treatment	2017	Past
Colonic polyps	Large intestine polyp	28APR2017	Present

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Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Neck strain	Muscle strain	14JUN2017	Past
Right Jaw pain	Pain in jaw	14JUN2017	Past
Penicillin Allergy	Drug hypersensitivity	2018	Present
Pre-syncope	Presyncope	2018	Past
Acute rhinitis	Rhinitis	11DEC2018	Past
Left hand inflammatory arthropathy	Arthropathy	MAR2019	Past
Acute bronchitis	Bronchitis	19MAR2019	Past
Concussion	Concussion	28MAY2019	Past
Frontal Scalp contusion	Contusion	28MAY2019	Past
Closed nasal bone fracture	Facial bones fracture	28MAY2019	Past
Periorbital hematoma	Periorbital haematoma	28MAY2019	Past
Urinary tract infection	Urinary tract infection	14AUG2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	11:09
2	BNT162b2	01SEP2020 (21)	12:18

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Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INV	Cardiac stress test abnormal	CARDIAC STRESS TEST ABNORMAL, HOSPITALIZED	08SEP2020 (28)		ONGOING			3	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Believed related to chronic conditions including hypertension and hyperlipidemia	2	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1940	80	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	86.23 kg	34.1 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Drug allergy - macrodantin	Drug hypersensitivity	1950	Present
Drug allergy - penicillin	Drug hypersensitivity	1950	Present
Endometriosis	Endometriosis	1960	Past
Tonsillectomy	Tonsillectomy	1961	Past
Tonsillitis	Tonsillitis	1961	Past
Allergic rhinitis	Rhinitis allergic	1972	Present
Familial tremors	Familial tremor	1974	Present
Recurrent joint pain, neck, shoulders, ankles, elbows, hips, knees, wrists	Arthralgia	1980	Present
Arthroscopy left knee	Arthroscopy	1980	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anal fistula	Anal fistula	1981	Past
Anal fistulectomy	Anal fistula repair	1981	Past
Chronic Obstructive Pulmonary Disease	Chronic obstructive pulmonary disease	1984	Present
Myopia - bilateral	Myopia	1984	Present
Presbyopia	Presbyopia	1984	Present
Obesity	Obesity	1985	Present
CPAP	Continuous positive airway pressure	1989	Present
Sleep apnea	Sleep apnoea syndrome	1989	Present
duodenal ulcer	Duodenal ulcer	1990	Past
heartburn	Dyspepsia	1990	Present
esophageal ulcer	Oesophageal ulcer	1990	Past
Tension headaches	Tension headache	1993	Present
Cholecystectomy	Cholecystectomy	1994	Past
cholelithiasis	Cholelithiasis	1994	Past
Hypercholesterolemia	Hypercholesterolaemia	1994	Present
Carpal tunnel release surgery, bilateral	Carpal tunnel decompression	1996	Past
Carpal tunnel syndrome, bilateral	Carpal tunnel syndrome	1996	Past
Osteoarthritis, bilateral hands and knees	Osteoarthritis	1997	Present
Tennis elbow	Epicondylitis	1998	Past
Gout	Gout	1998	Present
Trigger release surgery, left fourth finger	Tendon sheath incision	1999	Past
Left fourth trigger finger	Trigger finger	1999	Past
Diabetic neuropathy bilateral hands	Diabetic neuropathy	2000	Present
Diabetic neuropathy, bilateral lower extremities	Diabetic neuropathy	2000	Present
Anxiety	Anxiety	2001	Present
Depression	Depression	2001	Present

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Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Rosacea	Rosacea	26NOV2001	Present
Psoriasis	Psoriasis	2002	Present
Diabetes mellitus type 2	Type 2 diabetes mellitus	2002	Present
Urinary incontinence	Urinary incontinence	2002	Present
Fracture L. 5th toe	Foot fracture	2003	Past
Recurrent back pain - lumbar	Back pain	2004	Present
Heart murmur	Cardiac murmur	2004	Present
Hypertension	Hypertension	2004	Present
Hypothyroidism	Hypothyroidism	2004	Present
mitral valve regurgitation	Mitral valve incompetence	2005	Present
Uterine lesion - benign	Uterine disorder	2005	Past
Excision, uterine lesion	Uterine operation	2006	Past
Tendonitis, left wrist	Tendonitis	JAN2006	Past
Left wrist tendonitis repair	Tenoplasty	JAN2006	Past
Left knee arthroplasty	Knee arthroplasty	2007	Past
cyst, right ankle, benign	Arthropathy	2009	Past
Pneumonia	Pneumonia	MAR2009	Past
Fracture, right foot	Foot fracture	2010	Past
External hemorrhoids	Haemorrhoids	2010	Present
chronic constipation	Constipation	APR2010	Present
Cyst excision, right ankle	Ankle operation	JUL2010	Past
Fracture, right shoulder	Upper limb fracture	JUL2010	Past
Stress fracture, right ankle	Stress fracture	AUG2010	Past
Iron deficiency anemia	Iron deficiency anaemia	SEP2010	Past
bronchitis	Bronchitis	12NOV2010	Past
Dry mouth	Dry mouth	2012	Present

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Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteopenia	Osteopenia	2012	Present
Shoulder implant, right - insertion	Shoulder arthroplasty	2013	Past
Shoulder implant infection, right	Device related infection	2014	Past
Insomnia	Insomnia	2014	Present
Fibromyalgia	Fibromyalgia	APR2014	Present
Shoulder implant removal, right	Shoulder arthroplasty	APR2014	Past
Cataracts - bilateral	Cataract	2016	Past
Osteoporosis	Osteoporosis	2016	Present
atrial fibrillation	Atrial fibrillation	01NOV2017	Present
implantable loop recorder	Implantable cardiac monitor insertion	01NOV2017	Present
Chest Pain	Chest pain	2018	Present
Left rotator cuff tear	Rotator cuff syndrome	JAN2018	Past
Left rotator cuff repair surgery	Rotator cuff repair	01MAR2018	Past
Bilateral leg cramps	Muscle spasms	APR2018	Present
Chronic kidney disease stage III	Chronic kidney disease	25APR2018	Present
edema- bilateral lower extremities	Oedema peripheral	25APR2018	Present
nasal polyps	Nasal polyps	MAY2018	Present
Peripheral Vascular Disease	Peripheral vascular disorder	MAY2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	10:15
2	BNT162b2	01SEP2020 (22)	08:18

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Diarrhoea	Diarrhea	17AUG2020 (7)	00:00	27AUG2020 (17)	00:00	11	2
2	GASTR	Diarrhoea	Diarrhea	27AUG2020 (17)		29AUG2020 (19)		3	4
3	PSYCH	Mental status changes	Mental State Status Change	02OCT2020 (53)		02OCT2020 (53)		1	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (27AUG2020)	NOT RELATED/OTHER: Pre-Existing conditions	1	7	N
2	N	Y	Resolved (29AUG2020)	NOT RELATED/OTHER: Unknown	1	17	Y
3	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: unknown	2	32	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	06OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	72	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	87.27 kg	25.3 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
gastric reflux	Gastrooesophageal reflux disease	1975	Present
Presbyopia	Presbyopia	1997	Present
Prostate Cancer	Prostate cancer	2004	Past
Radical prostatectomy	Radical prostatectomy	2004	Past
vasectomy	Vasectomy	2004	Past
Coronary stent placement	Coronary arterial stent insertion	2008	Past
Coronary artery disease	Coronary artery disease	2008	Present
Hypercholesterolemia	Hypercholesterolaemia	2008	Present
Implantable Cardioverter Defibrillator		2015	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
cardiac arrest	Cardiac arrest	2015	Past
Coronary stent placement	Coronary arterial stent insertion	2015	Past
Coronary Artery Occlusion	Coronary artery occlusion	2015	Past
cholecystectomy	Cholecystectomy	2017	Past
Cholelithiasis	Cholelithiasis	2017	Past
Bladder Cancer	Bladder cancer	2019	Past
Cystoscopy	Cystoscopy	2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	08:37
2	BNT162b2	04SEP2020 (22)	06:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Asthenia	Weakness	27OCT2020 (75)		ONGOING			2
2	SURG	Cardioversion	Defibrillator Discharge	15OCT2020 (63)		15OCT2020 (63)		1	2

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Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Y	Yes	NOT RELATED/OTHER: Medical History of Heart Issues	2	54	Y
2	N	N	Resolved (15OCT2020)	NOT RELATED/OTHER: Implanted Defibrillator	2	42	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.82 cm	116.18 kg	39.7 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1960	Present
Leg Cramps	Muscle spasms	1972	Present
asthma	Asthma	1985	Present
Allergic Rhinitis	Rhinitis allergic	1986	Present
Hemorrhoids	Haemorrhoids	1990	Present
Gastric Reflux	Gastrooesophageal reflux disease	2000	Present
Hypercholesterolemia	Hypercholesterolaemia	2002	Present
Recurrent Back pain	Back pain	2010	Present
Osteoarthritis- knees	Osteoarthritis	2010	Present

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Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2016	Present
Atrial Fibrillation	Atrial fibrillation	30OCT2019	Present
sleep apnea	Sleep apnoea syndrome	NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	14:40
2	Placebo	22SEP2020 (22)	07:56

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Hepatic cancer metastatic	poorly differentiated carcinoma metastatic to liver, unknown primary	27OCT2020 (57)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: Unknown	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	53.5 kg	21.2 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1988	Present
Osteoarthritis - knees	Osteoarthritis	1995	Present
Allergic rhinitis	Rhinitis allergic	1995	Present
Hemorrhoids	Haemorrhoids	1998	Present
Anxiety	Anxiety	2001	Present
Cyst - bilateral breasts	Breast cyst	2001	Past
Cystectomy - bilateral breasts	Breast cyst excision	2001	Past
Insomnia	Insomnia	2005	Present
Bilateral carpal tunnel syndrome	Carpal tunnel syndrome	2006	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Recurrent lumbar pain	Back pain	2010	Present
Recurrent abdominal pain	Abdominal pain	2012	Present
Chronic constipation	Constipation	2012	Past
Asthma	Asthma	2013	Present
Osteoporosis	Osteoporosis	2013	Present
Septal deviation - nasal	Nasal septum deviation	AUG2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24SEP2020 (1)	13:40
2	Placebo	15OCT2020 (22)	11:09

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Road traffic accident	Motor Vehicle Collision	05NOV2020 (43)		ONGOING	

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Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		4	N	Y	Yes	NOT RELATED/OTHER: Vehicle Collision	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.37 cm	79.64 kg	28.7 kg/m2	05OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myopia	Myopia	1995	Present
Recurrent back pain lumbar	Back pain	1998	Present
Polycystic Kidney Disease	Congenital cystic kidney disease	1999	Present
Migraine	Migraine	2000	Present
allergic rhinitis	Rhinitis allergic	2010	Present
Biliary Colic	Biliary colic	2012	Past
cholecystectomy	Cholecystectomy	2012	Past
bilateral tubal ligation	Female sterilisation	2017	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05OCT2020 (1)	15:26

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Benign pancreatic neoplasm	Serous cystadenoma of Pancreas	24OCT2020 (20)		ONGOING			1
2	INFEC	Urinary tract infection	Urinary Tract Infection	15OCT2020 (11)		24OCT2020 (20)		10	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: unknown	1	20	N
2	N	Y	Resolved (24OCT2020)	NOT RELATED/OTHER: Pancreatic Mass Found	1	11	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05OCT2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	67.7 kg	28.5 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1959	Past
Tonsillitis	Tonsillitis	1959	Past
Seasonal Allergic Rhinitis	Seasonal allergy	1979	Present
Post Menopausal	Postmenopause	2000	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	16:44
2	BNT162b2	01OCT2020 (22)	15:06

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Cerebrovascular accident	Stroke (CVA)	02NOV2020 (54)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Yes	NOT RELATED/OTHER: not related to drug or non-drug treatment	2	33	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	30OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	77	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.29 cm	66.45 kg	25.5 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DRUG ALLERGY TO CODEINE SULFATE	Drug hypersensitivity	1961	Present
NICOTINE DEPENDENCE	Nicotine dependence	1980	Past
DRUG ALLERGY TO ZESTRIL	Drug hypersensitivity	1996	Present
HYPERTENSION	Hypertension	1996	Present
POSTMENOPAUSAL	Postmenopause	1996	Present
DRUG ALLERGY TO LOPRESSOR	Drug hypersensitivity	1998	Present
HYPERLIPIDEMIA	Hyperlipidaemia	2000	Present
OSTEOPOROSIS	Osteoporosis	2008	Present
DRUG ALLERGY TO FOSAMAX	Drug hypersensitivity	2009	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
LEFT BUNDLE BRANCH BLOCK	Bundle branch block left	2010	Present
PALPITATIONS	Palpitations	2010	Present
SHORTNESS OF BREATH	Dyspnoea	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	15:28
2	BNT162b2	12SEP2020 (24)	10:48

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Acute myeloid leukaemia	Acute Myeloid Leukemia	08NOV2020 (81)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: Unknown	2	58	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.47 cm	68.36 kg	25.2 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1985	Present
Asthma, Allergy Induced	Asthma	1992	Present
Amoxicillin Allergy	Drug hypersensitivity	1992	Present
Wisdom Teeth Extraction	Wisdom teeth removal	1994	Past
Ceftin Allergy	Drug hypersensitivity	1998	Present
Polycystic Ovarian Disease	Polycystic ovaries	2003	Present
Hyperlipidemia	Hyperlipidaemia	2015	Present
GERD	Gastrooesophageal reflux disease	2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Anxiety	Anxiety	AUG2016	Past
Hypothyroidism	Hypothyroidism	30AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	26AUG2020 (1)	10:01
2	Placebo	16SEP2020 (22)	10:55

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	REPRO	Breast mass	left breast lump	27AUG2020 (2)		29SEP2020 (35)		34
2	GASTR	Diarrhoea	diarrhea	01SEP2020 (7)		01SEP2020 (7)		1
3	GENRL	Injection site pain	left arm soreness at injection site.	27AUG2020 (2)		29AUG2020 (4)		3
4	NEOPL	Invasive ductal breast carcinoma	invasive ductal carcinoma stage 1B, left breast	30SEP2020 (36)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (29SEP2020)	NOT RELATED/OTHER: breast lump	1	2	N

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Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	2	N	N	Resolved (01SEP2020)	Study Treatment	1	7	N
3	2	N	N	Resolved (29AUG2020)	Study Treatment	1	2	N
4	2	N	Y	Yes	NOT RELATED/OTHER: breast cancer	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.04 cm	83 kg	31.9 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
environmental allergy	Hypersensitivity	1980	Present
asthma	Asthma	1984	Present
chronic back pain	Back pain	1989	Present
herpes simplex, genital	Genital herpes simplex	1990	Present
irritable bowel syndrome-constipation	Irritable bowel syndrome	1990	Present
drug abuse	Drug abuse	1999	Past
anxiety	Anxiety	2000	Present
depression	Depression	2000	Present
chronic vaginitis	Vaginal infection	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
lumbar facet syndrome	Facet joint syndrome	2013	Present
degenerative disc disease	Intervertebral disc degeneration	2013	Present
herniated disc	Intervertebral disc protrusion	2013	Present
cervical spondylosis	Spinal osteoarthritis	2014	Present
lumbar spondylosis	Spinal osteoarthritis	2014	Present
bilateral sacro-iliac joint dysfunction	Spondyloarthropathy	2014	Present
dyspareunia	Dyspareunia	2015	Present
hot flashes	Hot flush	2015	Present
insomnia	Insomnia	2015	Present
osteoarthritis	Osteoarthritis	2015	Present
obesity	Obesity	2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	11:50
2	BNT162b2	17SEP2020 (23)	16:03

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Fatigue	Fatigue	27AUG2020 (2)		03SEP2020 (9)		8
2	INJ&P	Upper limb fracture	Closed fracture of right elbow	28OCT2020 (64)	19:35	29OCT2020 (65)		2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	N	Resolved (03SEP2020)	Study Treatment	1	2	N
2	2	TC/TCN	Y	Resolved (29OCT2020)	NOT RELATED/OTHER: fall trauma	2	42	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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FDA-CBER-2021-5683-1787760

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
195.58 cm	123.18 kg	32.1 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
old sport injury R knee	Sports injury	1963	Past
Allergic rhinitis	Rhinitis allergic	2000	Present
Surgery on R knee	Knee operation	2006	Past
Hypertension	Hypertension	14MAR2009	Present
Male erective disorder	Erectile dysfunction	2010	Present
Lumbar radiculopathy	Lumbar radiculopathy	22DEC2015	Present
Impingement syndrome of R shoulder	Rotator cuff syndrome	23FEB2017	Present
Bursitis of R shoulder	Bursitis	20JUN2017	Present
Bilateral carpal tunnel syndrome	Carpal tunnel syndrome	20DEC2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hyperlipidemia	Hyperlipidaemia	27DEC2018	Present
Obesity	Obesity	2019	Present
Cataract surgery L eye	Cataract operation	MAR2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08SEP2020 (1)	09:41
2	BNT162b2	28SEP2020 (21)	09:07

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Fatigue	fatigue	09SEP2020 (2)	07:00	11SEP2020 (4)		3
2	GENRL	Injection site pain	Injection site tenderness	08SEP2020 (1)	12:00	11SEP2020 (4)		4
3	NERV	Ischaemic stroke	Acute Ischemic Stroke	04OCT2020 (27)	13:00	06OCT2020 (29)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (11SEP2020)	Study Treatment	1	2	N

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Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	1	N	N	Resolved (11SEP2020)	Study Treatment	1	1	N
3	2	N	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: unknown	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	72.73 kg	25.8 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2010	Present
ROTATOR CUFF REPAIR RIGHT SIDE	Rotator cuff repair	2012	Past
TORN ROTATOR CUFF RIGHT SIDE	Rotator cuff syndrome	2012	Past
ROTATOR CUFF REPAIR LEFT SIDE	Rotator cuff repair	2015	Past
TORN ROTATOR CUFF LEFT SIDE	Rotator cuff syndrome	2015	Past
BENIGN PROSTATIC HYPERPLASIA	Benign prostatic hyperplasia	2017	Present
HYPOTHYROIDISM	Hypothyroidism	2017	Present
ARTHROSCOPIC REPAIR LEFT SIDE	Arthroscopic surgery	2019	Past
TORN MENISCUS LEFT SIDE	Meniscus injury	DEC2019	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	18:17
2	BNT162b2	02OCT2020 (38)	09:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Arthralgia	Acute Pain hip right side	03SEP2020 (9)		02OCT2020 (38)		30
2	MUSC	Arthralgia	Right Shoulder Pain	03SEP2020 (9)		20OCT2020 (56)		48
3	INJ&P	Brain contusion	Left frontal lobe contusion	03SEP2020 (9)		02OCT2020 (38)		30
4	INJ&P	Fall	FALL	03SEP2020 (9)		03SEP2020 (9)		1
5	MUSC	Mobility decreased	Decreased Mobility	03SEP2020 (9)		20OCT2020 (56)		48
6	MUSC	Muscle spasms	Muscle Spasm	03SEP2020 (9)		02OCT2020 (38)		30
7	INJ&P	Pelvic fracture	Closed Fracture of Rt Interior Pubic Ramus	03SEP2020 (9)		02OCT2020 (38)		30
8	INJ&P	Rib fracture	Closed Fracture of Four Ribs	03SEP2020 (9)		02OCT2020 (38)		30
9	INJ&P	Scapula fracture	Closed Displaced Fracture of body Right Scapula	03SEP2020 (9)		20OCT2020 (56)		48
10	NERV	Subarachnoid haemorrhage	SUBARACHNOID HEMORRAGE	03SEP2020 (9)		ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	TC	N	Resolved (02OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
2	1	TC	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
3	1	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: fall from bicycle	1	9	N
4	1	TC	N	Resolved (03SEP2020)	NOT RELATED/OTHER: fall from bicycle	1	9	N
5	1	N	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
6	2	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
7	2	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
8	2	N	N	Resolved (02OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
9	2	N	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Bicycle Fall	1	9	N
10	3	TC	Y	Yes	NOT RELATED/OTHER: FALL	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	30OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.3 cm	71.8 kg	23.4 kg/m2	08SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08SEP2020 (1)	13:15
2	BNT162b2	28SEP2020 (21)	15:13

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	METAB	Hypokalaemia	Hypokalemia	23OCT2020 (46)		24OCT2020 (47)		2
2	METAB	Hypomagnesaemia	Hypomagnesemia	23OCT2020 (46)		24OCT2020 (47)		2
3	INJ&P	Muscle injury	Muscle Sprain (Right Leg)	23SEP2020 (16)		ONGOING		
4	INJ&P	Overdose	Heroin Overdose	23OCT2020 (46)		24OCT2020 (47)		2

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC	N	Resolved (24OCT2020)	NOT RELATED/OTHER: heroin overdose	2	26	N
2	2	TC	N	Resolved (24OCT2020)	NOT RELATED/OTHER: heroin overdose	2	26	N
3	1	TC	N	Yes	NOT RELATED/OTHER: unk	1	16	N
4	4	TC	Y	Resolved (24OCT2020)	NOT RELATED/OTHER: heroin overdose	2	26	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	26OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	100 kg	32.5 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral broken Knees	Lower limb fracture	1953	Past
Bilateral Hip Replacement	Hip arthroplasty	1990	Past
Hypothyroidism	Hypothyroidism	1999	Present
Angioplasty	Angioplasty	2000	Past
Joint Pain	Arthralgia	2000	Present
High Cholestrol	Blood cholesterol increased	2000	Present
Congestive Heart Failure	Cardiac failure congestive	2000	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2000	Present
Hypertension	Hypertension	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	2000	Present
Tinnitis	Tinnitus	2000	Present
Left Eye Vision Loss	Blindness unilateral	APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	15:25
2	BNT162b2	23SEP2020 (22)	14:40

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Cerebrovascular accident	Stroke	18OCT2020 (47)		ONGOING			3	N	Y
2	GASTR	Diarrhoea	diarrhea	24SEP2020 (23)	19:00	24SEP2020 (23)	23:00	1	1	N	N
3	GASTR	Nausea	nausea	24SEP2020 (23)	19:00	24SEP2020 (23)	23:00	1	1	N	N
4	GASTR	Vomiting	vomiting	24SEP2020 (23)	19:00	24SEP2020 (23)	23:00	1	1	N	N

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Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: medical history of hypertension and congestive heart failure	2	26	Y
2	Resolved (24SEP2020)	Study Treatment	2	2	N
3	Resolved (24SEP2020)	Study Treatment	2	2	N
4	Resolved (24SEP2020)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	88.64 kg	29.7 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	MAY2005	Past
appendicitis	Appendicitis	MAY2005	Past
abdominal scar	Scar	MAY2005	Present
bilateral lower legs edema 1+	Oedema peripheral	2015	Present
bilateral fungus toenails	Onychomycosis	2015	Present
nerve pain, cervical spine	Neuralgia	11SEP2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18SEP2020 (1)	11:50
2	Placebo	09OCT2020 (22)	11:22

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Aortic valve incompetence	acute severe aortic insufficiency	28OCT2020 (41)		ONGOING			4	TC/TCN	Y
2	CARD	Atrial fibrillation	intermittent atrial fibrillation	06NOV2020 (50)		ONGOING			2	TC	N
3	INFEC	Endocarditis bacterial	bacterial endocarditis	28OCT2020 (41)		ONGOING			2	TC	N
4	MUSC	Myalgia	pain L hamstring muscles	28OCT2020 (41)		ONGOING			2	TC	N
5	NERV	Subarachnoid haemorrhage	subarachnoid hemorrhage	05NOV2020 (49)		ONGOING			3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: gram positive cocci bacterial endocarditis, source unknown	2	20	Y
2	Yes	NOT RELATED/OTHER: bacterial endocarditis	2	29	N
3	Yes	NOT RELATED/OTHER: infection	2	20	N
4	Yes	NOT RELATED/OTHER: heavy lifting	2	20	N
5	Yes	NOT RELATED/OTHER: possibly secondary to underlying bacterial endocarditis (mycotic aneurysm)	2	28	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.8 cm	68.8 kg	22.8 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 diabetes	Type 2 diabetes mellitus	2005	Present
Diabetic neuropathy	Diabetic neuropathy	FEB2005	Present
Hyperlipidemia	Hyperlipidaemia	2010	Present
Hypertension	Hypertension	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	13:30
2	BNT162b2	21SEP2020 (22)	12:00

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis perforated	Perforated appendicitis	31AUG2020 (1)	19:00	16SEP2020 (17)		17
2	GENRL	Fatigue	Fatigue	21SEP2020 (22)	16:00	21SEP2020 (22)	20:00	1
3	GENRL	Injection site pain	Injection Site Pain	31AUG2020 (1)	18:00	03SEP2020 (4)	08:00	4
4	GENRL	Injection site pain	Injection site pain	22SEP2020 (23)	08:00	24SEP2020 (25)	08:00	3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (16SEP2020)	NOT RELATED/OTHER: bacterial infection	1	1	Y
2	1	N	N	Resolved (21SEP2020)	Study Treatment	2	1	N
3	1	N	N	Resolved (03SEP2020)	Study Treatment	1	1	N
4	1	N	N	Resolved (24SEP2020)	Study Treatment	2	2	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	104.3 kg	36.1 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	01APR1982	Present
Hypertension	Hypertension	01OCT2000	Present
Anomalous coronary artery	Congenital coronary artery malformation	2010	Present
Coronary artery bypass graft	Coronary artery bypass	2010	Past
Angina	Angina pectoris	24MAR2010	Past
Coronary vasospasm	Arteriospasm coronary	24MAR2010	Past
Hypertriglyceridemia	Hypertriglyceridaemia	01APR2010	Present
Redo of coronary bypass graft with re-implantation RCA and unroofing of LAD bridge	Coronary artery bypass	2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sinus tachycardia	Sinus tachycardia	01APR2019	Present
Type 2 diabetes	Type 2 diabetes mellitus	01FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03SEP2020 (1)	12:14
2	Placebo	23SEP2020 (21)	10:18

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Arteriospasm coronary	Coronary vasospasm	25SEP2020 (23)		26SEP2020 (24)		2	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (26SEP2020)	NOT RELATED/OTHER: underlying cardiac disease	2	3	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine	INFLUENZA VACCINE	09OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.5 cm	92.2 kg	34.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPOTHYROIDISM	Hypothyroidism	18MAR1993	Present
TYPE II DIABETES	Type 2 diabetes mellitus	18MAR1995	Present
OBESITY	Obesity	2000	Present
OSTEOARTHRITIS	Osteoarthritis	18MAR2003	Present
CHRONIC PAIN	Pain	18MAR2003	Present
POST MENOPAUSAL	Postmenopause	2008	Present
RIGHT HEMITHYROIDECTOMY	Thyroidectomy	2015	Past
CORONARY ARTERY BYPASS GRAFT	Coronary artery bypass	19AUG2018	Past
CORONARY ARTERY DISEASE	Coronary artery disease	19AUG2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	19AUG2018	Present
HYPERTENSION	Hypertension	19AUG2018	Present
MYOCARDIAL INFARCTION	Myocardial infarction	19AUG2018	Past
BILATERAL LEG EDEMA	Oedema peripheral	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	12:25
2	Placebo	09SEP2020 (22)	15:08

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Pneumonia	PNEUMONIA	20SEP2020 (33)		04OCT2020 (47)	08:00	15	2	TC

Adverse Events					
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (04OCT2020)	NOT RELATED/OTHER: COMMUNITY ACQUIRED PNEUMONIA	2	12	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	44	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.3 cm	128.4 kg	41.8 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ASTHMA	Asthma	1980	Present
PENICILLIN ALLERGY	Drug hypersensitivity	1985	Present
MIGRAINE HEADACHES	Migraine	1994	Present
CESAREAN SECTION	Caesarean section	20MAY1994	Past
CESAREAN SECTION	Caesarean section	24MAY1996	Past
BILATERAL TUBAL LIGATION	Female sterilisation	1999	Past
CESAREAN SECTION	Caesarean section	29NOV1999	Past
OBESITY	Obesity	2000	Present
UTERINE FIBROIDS	Uterine leiomyoma	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
BENIGN CARDIAC MASS	Benign cardiac neoplasm	NOV2008	Past
THORACTOMY WITH RESECTION OF BENIGN CARDIAC MASS	Cardiac operation	NOV2008	Past
OSTEOARTHRITIS BILATERAL KNEES	Osteoarthritis	2010	Present
GOITER	Goitre	2011	Past
HYPOTHYROIDISM	Hypothyroidism	2011	Present
THYROIDECTOMY	Thyroidectomy	2011	Past
MAJOR DEPRESSION	Major depression	2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	11:47
2	Placebo	01OCT2020 (31)	13:41

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NEOPL	Uterine leiomyoma	WORSENING OF UTERINE FIBROIDS	14SEP2020 (14)	08:00	19SEP2020 (19)	12:00	6	2	TCN	Y

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Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (19SEP2020)	NOT RELATED/OTHER: MEDICAL HISTORY OF UTERINE FIBROIDS	1	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155 cm	88.6 kg	36.9 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1970	Present
Cholecystectomy	Cholecystectomy	1985	Past
Cholelithiasis	Cholelithiasis	1985	Past
Seasonal Allergies	Seasonal allergy	1990	Present
Cesarean Section	Caesarean section	27JUL1999	Past
Obesity	Obesity	2000	Present
Hypertension	Hypertension	2002	Present
Cesarean Section	Caesarean section	23SEP2002	Past
Depression	Depression	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type II Diabetes Mellitus	Type 2 diabetes mellitus	2010	Present
Gastroesophageal Reflux Disease	Gastrooesophageal reflux disease	2011	Present
Chronic Obstructive Pulmonary Disease	Chronic obstructive pulmonary disease	2014	Present
Post Menopausal	Postmenopause	2016	Present
Dyslipidemia	Dyslipidaemia	2017	Present
Coronary Artery Stent Placement	Coronary arterial stent insertion	28MAY2017	Past
Myocardial Infarction	Myocardial infarction	28MAY2017	Past
Bilateral Hands Carpal Tunnel Syndrome	Carpal tunnel syndrome	2019	Present
Left Wrist Carpal Tunnel Surgery	Carpal tunnel decompression	OCT2019	Past
Right Wrist Carpal Tunnel Surgery	Carpal tunnel decompression	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	11:17
2	Placebo	04NOV2020 (20)	14:00

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Peritonsillar abscess	PENTONSILLAR ABSESS	22OCT2020 (7)		ONGOING			3

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Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown at this time, awaiting medical records	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	81.82 kg	30.9 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis	Osteoarthritis	2005	Present
Carotid Artery Disease	Carotid artery disease	2013	Present
Hypercholesterolemia	Hypercholesterolaemia	2013	Present
Hypertension	Hypertension	2013	Present
Heartburn	Dyspepsia	2015	Present
Hodgkin's Lymphoma	Hodgkin's disease	JUN2016	Past
Non-Hodgkins's Lymphoma	Non-Hodgkin's lymphoma	JUN2016	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	17:35
2	BNT162b2	23SEP2020 (38)	16:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Transient ischaemic attack	Transient Ischaemic Attack	04SEP2020 (19)		09SEP2020 (24)		6	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: carotid artery disease	1	19	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187 cm	100.9 kg	28.9 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to Codeine	Drug hypersensitivity	1960	Present
Tonsillectomy	Tonsillectomy	1960	Past
Appendectomy	Appendicectomy	1964	Past
Hernia Repair	Hernia repair	1970	Past
Hernia Repair	Hernia repair	1978	Past
Testicular Cancer	Testis cancer	1982	Past
Low Testosterone	Blood testosterone decreased	1983	Present
Hypercholesterolemia	Hypercholesterolaemia	2000	Present
Hypertension	Hypertension	2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 Diabetes	Type 2 diabetes mellitus	2005	Present
Deep Vein Thrombosis	Deep vein thrombosis	2010	Present
Depression	Depression	2010	Present
Pressure in Eyes	Ocular discomfort	2018	Present
Erectile Dysfunction	Erectile dysfunction	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	11:33
2	Placebo	29SEP2020 (28)	13:13

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	EYE	Retinal artery occlusion	Central Retinal Artery Occlusion	29SEP2020 (28)	15:30	ONGOING			1	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Pre-existing medical conditions,hypercoagulable state due to hypertension, TIID	2	1	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	85.91 kg	29.6 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Post Menopausal	Postmenopause	2000	Present
Seasonal Allergies	Seasonal allergy	2000	Present
Osteoarthritis, right knee	Osteoarthritis	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	15:36
2	BNT162b2	25SEP2020 (22)	14:38

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Aphasia	Expressive Aphasia	22OCT2020 (49)		26OCT2020 (53)		5	2
2	NERV	Cerebrovascular accident	CVA	22OCT2020 (49)		26OCT2020 (53)		5	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (26OCT2020)	NOT RELATED/OTHER: Pending medical records	2	28	N
2	N	Y	Resolved (26OCT2020)	NOT RELATED/OTHER: PENDING MEDICAL RECORDS	2	28	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1942	77	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156.5 cm	66.5 kg	27.2 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fibromyalgia	Fibromyalgia	1990	Present
Hypertension	Hypertension	1995	Present
Torn Meniscus	Meniscus injury	2005	Past
Bilateral Inguinal Hernia	Inguinal hernia	JUL2006	Present
Knee Replacement, Left Leg	Knee arthroplasty	JAN2011	Past
Upset Stomach	Abdominal discomfort	2012	Present
Insomnia	Insomnia	2012	Present
Dermatographia	Mechanical urticaria	2018	Present
Dry Eyes, Bilateral	Dry eye	2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	13:42
2	Placebo	01SEP2020 (22)	12:20

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Gastrointestinal disorder	Bowel Problems	31OCT2020 (82)		ONGOING			3	TC/TCN	Y
2	MUSC	Osteoarthritis	Osteoarthritis of the knee	26OCT2020 (77)		26OCT2020 (77)		1	3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: A confirmed possible etiology will be entered once it is known.	2	61	Y
2	Resolved (26OCT2020)	NOT RELATED/OTHER: Osteoarthritis of the knee which led to knee replacement	2	56	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	135.4 kg	48.5 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Histerectomy	Hysterectomy	1974	Past
Growth on Thyroid	Thyroid neoplasm	1974	Past
Fibroids	Uterine leiomyoma	1974	Past
Partial Thyroidectomy	Thyroidectomy	1975	Past
Hypothyroid	Hypothyroidism	1984	Present
Obesity	Obesity	1990	Present
Arrhythmia- A-Fib	Atrial fibrillation	1996	Present
Acid Reflux	Gastrooesophageal reflux disease	1997	Present
Hiatal Hernia	Hiatus hernia	1997	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Left Knee Replacement Surgery	Knee arthroplasty	1998	Past
Seasonal Allergies	Seasonal allergy	2000	Present
Hypertension	Hypertension	2008	Present
Right Knee Replacement Surgery	Knee arthroplasty	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	09:46
2	BNT162b2	01OCT2020 (28)	08:28

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	METAB	Fluid retention	Worsening of WATER RETENTION in lower extremities	16SEP2020 (13)		18SEP2020 (15)		3
2	VASC	Hypertension	Worsening of HYPERTENSION	16SEP2020 (13)		18SEP2020 (15)		3

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Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: UNKNOWN	1	13	Y
2	3	TC	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: UNKNOWN	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	02NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	117.91 kg	41.9 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	1962	Present
Seasonal Allergies	Seasonal allergy	1972	Present
Hypothyroidism	Hypothyroidism	1984	Present
Hypertension	Hypertension	1987	Present
Adrenal Hyperplasia	Hyperplasia adrenal	1997	Present
Bilateral Carpal Tunnel Surgery	Carpal tunnel decompression	2002	Past
Carpal Tunnel Syndrome- Bilateral	Carpal tunnel syndrome	2002	Present
Dyslipidemia	Dyslipidaemia	2002	Present
Gallstones	Cholelithiasis	FEB2002	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cholecystectomy	Cholecystectomy	2003	Past
Total Knee Replacement Right Knee	Knee arthroplasty	2003	Past
Osteoarthritis of Right Thumb	Osteoarthritis	2003	Present
Osteoarthritis-Bilateral Knees	Osteoarthritis	2003	Present
Fracture-Bilateral Wrists	Wrist fracture	2007	Past
Squamous Cell Skin Cancer removed from Nose	Skin neoplasm excision	2010	Past
Skin Cancer-Squamous Cell on Nose	Squamous cell carcinoma of skin	2010	Past
Anemia	Anaemia	2011	Past
Colon Polyps- Benign	Large intestine polyp	2011	Past
Colonoscopy/Removal of Benign Colon Polyps	Large intestinal polypectomy	01DEC2011	Past
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	11:49
2	BNT162b2	02SEP2020 (22)	11:06

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Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Abdominal pain lower	lower abdominal pain	11OCT2020 (61)		16OCT2020 (66)		6	3	TC/TCN	N
2	BLOOD	Anaemia	Worsening of Anemia	11OCT2020 (61)		29OCT2020 (79)		19	3	N	N
3	NEOPL	Borderline serous tumour of ovary	Serous borderline tumor of left ovary	11OCT2020 (61)		16OCT2020 (66)		6	3	TC/TCN	Y
4	GASTR	Diarrhoea	Diarrhea	13AUG2020 (2)		17AUG2020 (6)		5	1	N	N
5	INFEC	Urinary tract infection	Urinary Tract Infection	05OCT2020 (55)		16OCT2020 (66)		12	1	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (16OCT2020)	NOT RELATED/OTHER: Neoplasm of uncertain behavior of left ovary	2	40	N
2	Resolved (29OCT2020)	NOT RELATED/OTHER: Tumor of left ovary	2	40	N
3	Resolved (16OCT2020)	NOT RELATED/OTHER: Cancerous	2	40	Y
4	Resolved (17AUG2020)	NOT RELATED/OTHER: idiopathic	1	2	N
5	Resolved (16OCT2020)	NOT RELATED/OTHER: Idiopathic	2	34	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.75 cm	72.82 kg	28.8 kg/m2	13AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma-Stable, No change within 6 weeks of screening	Asthma	1980	Present
Seasonal Allergies	Seasonal allergy	1980	Present
C-Section	Caesarean section	1991	Past
Bilateral Tubal Ligation	Female sterilisation	1991	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	13AUG2020 (1)	15:09
2	BNT162b2	03SEP2020 (22)	15:38

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	Appendicitis	21AUG2020 (9)		23AUG2020 (11)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (23AUG2020)	NOT RELATED/OTHER: Acute Infection	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13AUG2020	
Completed	VACCINATION	01OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.47 cm	92.95 kg	34.3 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy-Sulfa	Drug hypersensitivity	1989	Present
Blood Transfusion	Transfusion	1989	Past
Allergy-Shellfish-Hives	Urticaria	1989	Present
Hysterectomy	Hysterectomy	1999	Past
Anxiety	Anxiety	2000	Present
Obesity	Obesity	2003	Present
Chronic Bronchitis-Stable	Bronchitis chronic	2005	Present
Hypertension	Hypertension	2008	Present
Insomnia	Insomnia	2008	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	2009	Present
Allergy-Dilaudid-itching	Pruritus allergic	2010	Present
Pneumonia	Pneumonia	2011	Past
Abdominal Hernia	Abdominal hernia	2012	Past
Abdominal Hernia Repair	Abdominal hernia repair	2012	Past
Chronic Back Pain	Back pain	2014	Present
Osteoarthritis of Left Knee	Osteoarthritis	2014	Present
Pneumonia	Pneumonia	2014	Past
Sleep Apnea	Sleep apnoea syndrome	2014	Present
Osteoarthritis of Low Back	Spinal osteoarthritis	2014	Present
Dyslipidemia	Dyslipidaemia	2016	Present
Presbyopia	Presbyopia	2016	Present
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	2016	Present
Abdominal Hernia Repair	Abdominal hernia repair	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	11:32
2	BNT162b2	09SEP2020 (24)	10:49

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Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	METAB	Hyperglycaemia	Hyperglycemic episode	17SEP2020 (32)		18SEP2020 (33)		2	3	N

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: self-induced due to watermelon diet	2	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1939	81	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.45 cm	65.64 kg	22.3 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1957	Present
Osteopenia-stable since 2016	Osteopenia	1985	Present
Hysterectomy	Hysterectomy	1989	Past
Migraine	Migraine	1990	Present
Chronic Urinary Tract Infections	Urinary tract infection	2000	Present
Hypothyroidism	Hypothyroidism	AUG2009	Present
Osteoarthritis of bilateral hands	Osteoarthritis	2013	Present
Rosacea	Rosacea	2013	Present
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2014	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Skin Cancer- Left Arm	Skin cancer	2014	Past
Skin Cancer-Right Leg	Skin cancer	2014	Past
Raynaud's Disease- No associated autoimmune conditions	Raynaud's phenomenon	2016	Present
Sleep Apnea	Sleep apnoea syndrome	APR2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	12:34
2	BNT162b2	16SEP2020 (22)	10:13

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INFEC	Empyema	loculated empyema	11OCT2020 (47)		ONGOING	
2	INFEC	Pneumonia	Right lower lobe pneumonia	11OCT2020 (47)		ONGOING	

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Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		3	TC	Y	Yes	NOT RELATED/OTHER: idiopathic	2	26	Y
2		3	TC	Y	Yes	NOT RELATED/OTHER: idiopathic	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	110.82 kg	35 kg/m2	31AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	12:15
2	Placebo	22SEP2020 (23)	12:18

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	CARD	Myocardial infarction	Myocardial Infarction	21OCT2020 (52)		ONGOING		
2	METAB	Type 2 diabetes mellitus	New Onset Type II Diabetes Mellitus	21OCT2020 (52)		ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	TC/TCN	Y	Yes	NOT RELATED/OTHER: Cardiac Event	2	30	Y
2	3	TC	Y	Yes	NOT RELATED/OTHER: Insulin Resistance	2	30	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174.5 cm	87.3 kg	28.7 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
diabetes mellitus type II	Type 2 diabetes mellitus	2004	Past
hyperopia	Hypermetropia	2005	Present
presbyopia	Presbyopia	2005	Present
gastric bypass surgery	Gastric bypass	2009	Past
benign prostate hyperplasia	Benign prostatic hyperplasia	2012	Past
prostatic surgery	Prostatic operation	2012	Past
spinal fusion	Spinal fusion surgery	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07AUG2020 (1)	12:28
2	BNT162b2	28AUG2020 (22)	11:08

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholelithiasis	cholelithiasis	13AUG2020 (7)		15AUG2020 (9)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (15AUG2020)	NOT RELATED/OTHER: concurrent illness	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181.5 cm	120 kg	36.4 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left ankle fracture	Ankle fracture	1988	Past
left ankle open reduction internal fixation	Open reduction of fracture	1988	Past
arthritis	Arthritis	2000	Present
arthritis, bilateral knee	Arthritis	2000	Past
idiopathic peripheral neuropathy	Neuropathy peripheral	2000	Present
allergy to amitriptyline	Drug hypersensitivity	2005	Past
left knee replacement	Knee arthroplasty	2013	Past
COPD	Chronic obstructive pulmonary disease	2015	Present
right knee replacement	Knee arthroplasty	2015	Past

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Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	2016	Past
appendicitis	Appendicitis	2016	Past
cataracts, bilateral	Cataract	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	14:51
2	Placebo	01SEP2020 (22)	13:35

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	METAB	Diabetes mellitus	diabetes	05NOV2020 (87)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TC	Y	Yes	NOT RELATED/OTHER: etiology unknown	2	66	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.15 cm	124.18 kg	36.5 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	1986	Present
Sleep Apnea	Sleep apnoea syndrome	2014	Present
Allergic Rhinitis-Seasonal	Seasonal allergy	2016	Present
Hypertension	Hypertension	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	12:40
2	Placebo	23SEP2020 (20)	14:51

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Atrial fibrillation	New Onset Atrial Fibrillation with rapid ventricular response	26OCT2020 (53)	00:00	ONGOING		
2	GENRL	Chest pain	Chest Pain	26OCT2020 (53)	00:00	28OCT2020 (55)	00:00	3
3	CARD	Mitral valve incompetence	Trivial Mitral Regurgitation	26OCT2020 (53)	00:00	ONGOING		
4	CARD	Palpitations	Heart Palpitations	26OCT2020 (53)	00:20	28OCT2020 (55)	00:00	3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Yes	NOT RELATED/OTHER: Arrhythmia	2	34	Y
2	2	TC	N	Resolved (28OCT2020)	NOT RELATED/OTHER: Arrhythmia	2	34	N
3	1	TC	N	Yes	NOT RELATED/OTHER: Heart Disease	2	34	N
4	2	TC	N	Resolved (28OCT2020)	NOT RELATED/OTHER: Arrhythmia	2	34	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	56	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.7 cm	73.35 kg	27.4 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Headaches	Headache	1983	Present
Decreased visual acuity	Visual acuity reduced	2003	Present
spine tumor	Bone neoplasm	2004	Past
Tumor removal surgery, from spine	Spinal operation	2004	Past
Amoxicillin Allergy	Drug hypersensitivity	2005	Present
Post-Menopausal	Postmenopause	2005	Present
Seasonal Allergies	Seasonal allergy	2005	Present
Hemangioma on Liver	Haemangioma of liver	2009	Past
hemangioma removal surgery	Haemangioma removal	2009	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Morphine Allergy	Drug hypersensitivity	2010	Present
benign mass from bottom of right foot removal surgery	Foot operation	2010	Past
benign mass from bottom of right foot	Limb mass	2010	Past
Tumor removal surgery, from mouth	Oral cavity neoplasm surgery	2010	Past
tumor in mouth	Oral neoplasm	2010	Past
Vertigo	Vertigo	2010	Present
Situational Depression	Adjustment disorder with depressed mood	01MAY2020	Present
Prolapsed Bladder	Bladder prolapse	01MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	16:53
2	BNT162b2	09SEP2020 (24)	13:47

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	REPRO	Ovarian cyst	Left ovarian cyst, benign tumor	24AUG2020 (8)		19SEP2020 (34)		27	2	TC/TCN	Y
2	REPRO	Uterine prolapse	Prolapsed uterus	24AUG2020 (8)		19SEP2020 (34)		27	2	TC/TCN	Y

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Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (19SEP2020)	NOT RELATED/OTHER: medical condition	1	8	Y
2	Resolved (19SEP2020)	NOT RELATED/OTHER: per PI Unknown, this is second time this has happened.Documentation is in medhx	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	30	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178.6 cm	94 kg	29.5 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	1995	Present
hernia	Hernia	1998	Past
hernia repair	Hernia repair	1998	Past
inflammation	Inflammation	1998	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	13:47
2	BNT162b2	25SEP2020 (29)	09:24

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Cellulitis	Cellulitis in Left leg	08SEP2020 (12)		16SEP2020 (20)		9	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (16SEP2020)	NOT RELATED/OTHER: BACTERIAL INFECTION	1	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	26OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	46	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169.5 cm	96.2 kg	33.5 kg/m2	14OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
AMOXIXILLIN ALLERGY	Drug hypersensitivity	1986	Present
BETADINE ALLERGY	Drug hypersensitivity	1986	Present
BILATERAL DECREASED VISUAL ACUITY	Visual acuity reduced	1987	Present
HEADACHES	Headache	1991	Present
GENERAL MUSCLE PAINS	Myalgia	1991	Present
SEASONAL ALLERGIES	Seasonal allergy	2000	Present
LEFT BICEP TENDON TEAR	Tendon rupture	MAR2006	Past
LEFT BICEP TENDON REPAIR	Tenoplasty	MAR2006	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ABDOMINAL HERNIA	Abdominal hernia	SEP2019	Past
ABDOMINAL HERNIA REPAIR	Abdominal hernia repair	SEP2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14OCT2020 (1)	12:42
2	Placebo	02NOV2020 (20)	10:16

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Acute coronary syndrome	Acute Coronary Syndrome	26OCT2020 (13)		26OCT2020 (13)		1	3	TC/TCN	N
2	CARD	Acute myocardial infarction	ST-segment elevated MYOCARDIAL INFARCTION	26OCT2020 (13)	07:30	26OCT2020 (13)	15:55	1	2	TC	Y
3	INV	Blood creatinine increased	Elevated Creatinine	26OCT2020 (13)		27OCT2020 (14)		2	1	N	N
4	METAB	Hyperglycaemia	Hyperglycemia	26OCT2020 (13)		27OCT2020 (14)		2	1	N	N
5	VASC	Hypertensive urgency	Hypertensive Urgency	26OCT2020 (13)		29OCT2020 (16)		4	2	TC	N

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Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (26OCT2020)	NOT RELATED/OTHER: ST-Segment Elevated Myocardial Infarction	1	13	N
2	Resolved (26OCT2020)	NOT RELATED/OTHER: previously undiagnosed coronary artery disease	1	13	Y
3	Resolved (27OCT2020)	NOT RELATED/OTHER: ST-segment elevated myocardial infarction	1	13	N
4	Resolved (27OCT2020)	NOT RELATED/OTHER: ST-segment elevated myocardial infarction	1	13	N
5	Resolved (29OCT2020)	NOT RELATED/OTHER: ST-segment elevated myocardial infarction	1	13	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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FDA-CBER-2021-5683-1787843

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14OCT2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	85.91 kg	29.6 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroidism	Hypothyroidism	1990	Present
vasectomy	Vasectomy	1996	Past
hypertension	Hypertension	2015	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	16:23
2	Placebo	23SEP2020 (24)	16:41

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Fall	Fall in hole	17OCT2020 (48)		17OCT2020 (48)		1	1
2	INJ&P	Lower limb fracture	Left leg fracture of tibia/fibula	17OCT2020 (48)		18OCT2020 (49)		2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (17OCT2020)	NOT RELATED/OTHER: Fall in hole	2	25	N
2	TC/TCN	Y	Resolved (18OCT2020)	NOT RELATED/OTHER: STEPPING IN HOLE	2	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1940	80	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	80.8 kg	31.6 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ALLERGY TO CODEINE	Drug hypersensitivity	1970	Present
FOOD ALLERGY TO ALCOHOL	Food allergy	1980	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	1980	Present
MIGRAINE HEADACHES	Migraine	1980	Present
NAUSEA	Nausea	1980	Present
OBESITY	Obesity	1980	Present
HEARING PROBLEMS (BILATERAL EARS)	Auditory disorder	1990	Present
FOOD ALLERGY TO SHRIMP	Food allergy	1990	Present
GOUT	Gout	1990	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERLIPIDEMIA	Hyperlipidaemia	1992	Present
HYPERTENSION	Hypertension	1992	Present
CONGESTIVE HEART FAILURE (CLASS 2)	Cardiac failure congestive	1995	Present
CHRONIC OBSTRUCTIVE PULMONARY DISEASE	Chronic obstructive pulmonary disease	1995	Present
CORONARY ARTERY DISEASE	Coronary artery disease	1995	Present
SHORTNESS OF BREATH	Dyspnoea	1995	Present
MITRAL VALVE DISORDER	Mitral valve disease	1998	Present
ANEMIA	Anaemia	2000	Present
CHRONIC KIDNEY DISEASE (STAGE 3)	Chronic kidney disease	2000	Present
DEPRESSION	Depression	2000	Present
OSTEOARTHRITIS (BILATERAL FEET)	Osteoarthritis	2000	Present
OSTEOARTHRITIS (BILATERAL HANDS)	Osteoarthritis	2000	Present
OSTEOARTHRITIS (BILATERAL LEGS)	Osteoarthritis	2000	Present
OSTEOPOROSIS	Osteoporosis	2000	Present
POST MENOPAUSAL	Postmenopause	2000	Present
SEASONAL ALLERGIC RHINITIS	Seasonal allergy	2000	Present
SLEEP APNEA	Sleep apnoea syndrome	2005	Present
RECURRENT CONSTIPATION	Constipation	2010	Present
DIABETIC NEUROPATHY	Diabetic neuropathy	2010	Present
TYPE 2 DIABETES	Type 2 diabetes mellitus	2010	Present
TREMOR (BILATERAL ARMS)	Tremor	2016	Present
MEMORY LOSS	Amnesia	2018	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07AUG2020 (1)	17:04
2	BNT162b2	26AUG2020 (20)	14:23

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain	Functional Abdominal Pain	28OCT2020 (83)		05NOV2020 (91)		9	2
2	GASTR	Diverticulum	Diverticulosis	28OCT2020 (83)		ONGOING			2
3	GENRL	Fatigue	Fatigue	31AUG2020 (25)		01SEP2020 (26)		2	1
4	HEPAT	Gallbladder disorder	Distended Gallbladder	28OCT2020 (83)		ONGOING			1
5	GASTR	Hiatus hernia	Small Hiatal Hernia	28OCT2020 (83)		ONGOING			1
6	NERV	Toxic encephalopathy	Acute Toxic Metabolic Encephalopathy	28OCT2020 (83)		05NOV2020 (91)		9	3
7	INFEC	Urinary tract infection	Urinary Tract Infection	28OCT2020 (83)		05NOV2020 (91)		9	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (05NOV2020)	NOT RELATED/OTHER: Diverticulosis	2	64	N
2	N	N	Yes	NOT RELATED/OTHER: Poor Diet	2	64	N
3	N	N	Resolved (01SEP2020)	Study Treatment	2	6	N
4	N	N	Yes	NOT RELATED/OTHER: Idiopathic	2	64	N
5	N	N	Yes	NOT RELATED/OTHER: Idiopathic	2	64	N

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	TC	Y	Resolved (05NOV2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	64	Y
7	N	N	Resolved (05NOV2020)	NOT RELATED/OTHER: Probable Bacterial Infection	2	64	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	23SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1960	59	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	78.8 kg	33.9 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	1985	Present
CHRONIC BACK PAIN	Back pain	1995	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	1995	Present
TRAUMATIC BRAIN INJURY	Craniocerebral injury	2000	Present
GLAUCOMA	Glaucoma	2005	Present
POST-MENOPAUSAL	Postmenopause	2005	Present
ALLERGY TO NUCYNTA	Drug hypersensitivity	2010	Present
CORONARY ARTERY DISEASE	Coronary artery disease	2012	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11AUG2020 (1)	15:37
2	Placebo	01SEP2020 (22)	14:05

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute coronary syndrome	ACUTE CORONARY SYNDROME	08SEP2020 (29)		10SEP2020 (31)		3	3
2	CARD	Angina unstable	UNSTABLE ANGINA	08SEP2020 (29)		10SEP2020 (31)		3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (10SEP2020)	NOT RELATED/OTHER: CORONARY ARTERY DISEASE	2	8	Y
2	N	N	Resolved (10SEP2020)	NOT RELATED/OTHER: CORONARY ARTERY DISEASE	2	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	22SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.9 cm	127.7 kg	38.2 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DEEP VEIN THROMBOSIS	Deep vein thrombosis	1994	Present
ALLERGY TO CODEINE	Drug hypersensitivity	2010	Present
ALLERGY TO CORTISONE	Drug hypersensitivity	2010	Present
CHRONIC BACK PAIN	Back pain	2018	Present
HYPERTENSION	Hypertension	2018	Present
NEUROPATHY (BILATERAL LEGS)	Neuropathy peripheral	2018	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	11:14
2	BNT162b2	09SEP2020 (20)	16:59

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Pharyngitis streptococcal	STREP THROAT	01SEP2020 (12)		05SEP2020 (16)		5	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (05SEP2020)	NOT RELATED/OTHER: BACTERIAL INFECTION	1	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	76.4 kg	27.4 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
headaches	Headache	2009	Present
allergic rhinitis	Rhinitis allergic	2015	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18SEP2020 (1)	10:08
2	BNT162b2	09OCT2020 (22)	13:41

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Meningioma	right frontal meningioma	23SEP2020 (6)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: unknown	1	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.96 cm	98.55 kg	27.8 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
tonsillectomy	Tonsillectomy	1953	Past
tonsillitis	Tonsillitis	1953	Past
left knee arthroscopy	Arthroscopy	1991	Past
osteoarthritis	Osteoarthritis	1991	Present
vasectomy	Vasectomy	1991	Past
gastroparesis	Impaired gastric emptying	1995	Present
dizziness	Dizziness	2000	Present
left knee arthroscopy	Arthroscopy	2001	Past
right knee arthroscopy	Arthroscopy	2001	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
elevated cholesterol	Blood cholesterol increased	2010	Present
right knee arthroscopy	Arthroscopy	2015	Past
hypertension	Hypertension	2015	Present
stroke	Cerebrovascular accident	2017	Past
watchman installed	Atrial appendage closure	2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	10:39
2	Placebo	09SEP2020 (22)	12:35

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Atrial fibrillation	Chronic atrial fibrillation with RVR'	04OCT2020 (47)		05OCT2020 (48)		2	3	TC/TCN	Y

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Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (05OCT2020)	NOT RELATED/OTHER: subject is 71 years old and susceptible to heart issues	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flu vaccine	INFLUENZA VACCINE	01OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	68.27 kg	23.5 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
abdominal surgery	Abdominal operation		Past
arthritis	Arthritis		Present
asthma	Asthma		Present
Atrial Fibrillation	Atrial fibrillation		Present
Lymph node biopsy	Biopsy lymph gland		Past
stroke	Cerebrovascular accident		Past
undescended testicle right	Cryptorchism		Past
amoxicillin drug allergy	Drug hypersensitivity		Present
codeine drug allergy	Drug hypersensitivity		Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
erythromycin drug allergy	Drug hypersensitivity		Present
penicillin drug allergy	Drug hypersensitivity		Present
beans food allergy	Food allergy		Present
hernia repair	Hernia repair		Past
hypertension	Hypertension		Present
funnel chest	Pectus excavatum		Present
PTSD	Post-traumatic stress disorder		Present
Seizure disorder	Seizure		Present
testicle exploration right	Testes exploration		Past
borderline personality disorder	Borderline personality disorder	2014	Present
COPD	Chronic obstructive pulmonary disease	17DEC2014	Present
schizophrenia	Schizophrenia	03NOV2017	Present
Polysubstance Abuse	Substance abuse	17AUG2018	Present
skin rash	Rash	27JUL2020	Present
left hand fracture	Hand fracture	12AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	14:22

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Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	RESP	Chronic obstructive pulmonary disease	worsening of COPD	26AUG2020 (2)		27AUG2020 (3)		2	2
2	INJ&P	Fall	Fall	09SEP2020 (16)	03:00	09SEP2020 (16)	03:00	1	2
3	INJ&P	Hip fracture	Left Hip Closed Fracture	09SEP2020 (16)	03:00	25SEP2020 (32)		17	3
4	GASTR	Nausea	nausea	27SEP2020 (34)		28SEP2020 (35)		2	2
5	PSYCH	Psychotic disorder	Psychosis	27SEP2020 (34)		ONGOING			3
6	PSYCH	Substance abuse	worsening of polysubstance abuse	27SEP2020 (34)		28SEP2020 (35)		2	2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (27AUG2020)	NOT RELATED/OTHER: Med HX of COPD	1	2	N
2	N	N	Resolved (09SEP2020)	NOT RELATED/OTHER: fall from dumpster	1	16	N
3	TC	Y	Resolved (25SEP2020)	NOT RELATED/OTHER: Fall	1	16	Y
4	N	N	Resolved (28SEP2020)	NOT RELATED/OTHER: subject detoxing from substance use	1	34	N
5	TC/TCN	Y	Yes	NOT RELATED/OTHER: Hx of mental disorders	1	34	Y
6	N	N	Resolved (28SEP2020)	NOT RELATED/OTHER: medical history of polysubstance abuse	1	34	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	102 kg	33.3 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Prostate Cancer	Prostate cancer	1988	Past
Sleep Apnea	Sleep apnoea syndrome	1990	Present
Chronic Myeloid Leukemia	Chronic myeloid leukaemia	1991	Present
Hypertension	Hypertension	2000	Present
Elevated Lipids	Lipids increased	2019	Present
chronic kidney disease, mild	Chronic kidney disease	AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	13:30
2	Placebo	21SEP2020 (20)	10:13

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	IMMUN	Anaphylactic shock	anaphylactic shock	09OCT2020 (38)		09OCT2020 (38)		1	4
2	INJ&P	Arthropod bite	ant bite, left ankle	09SEP2020 (8)	15:00	10SEP2020 (9)		2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (09OCT2020)	NOT RELATED/OTHER: anaphylactic shock to ant bite	2	19	Y
2	N	N	Resolved (10SEP2020)	NOT RELATED/OTHER: NA	1	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
181 cm	84.6 kg	25.8 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	1976	Present
chest pain	Chest pain	2008	Past
cyst in esophagus	Oesophageal cyst	2008	Past
removal of esophageal cyst	Oesophageal lesion excision	2008	Past
DVT	Deep vein thrombosis	2017	Past
restless leg syndrome	Restless legs syndrome	2017	Present
depression	Depression	OCT2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	11:43
2	Placebo	17SEP2020 (21)	10:02

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Diarrhoea	Diarrhea	17SEP2020 (21)		03OCT2020 (37)		17	1
2	RESP	Hypoxia	hypoxia	26SEP2020 (30)		27SEP2020 (31)		2	3
3	RESP	Nasal congestion	nasal congestion	10OCT2020 (44)		17OCT2020 (51)	10:00	8	1
4	RESP	Pneumonia aspiration	Aspiration Pneumonia	26SEP2020 (30)		06OCT2020 (40)		11	3
5	INJ&P	Toxicity to various agents	poisoning by cocaine	26SEP2020 (30)		27SEP2020 (31)		2	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (03OCT2020)	Study Treatment	2	1	N
2	TC/TCN	Y	Resolved (27SEP2020)	NOT RELATED/OTHER: opioid overdose	2	10	Y
3	N	N	Resolved (17OCT2020)	NOT RELATED/OTHER: environmental irritant	2	24	N
4	TC	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: poisoning by cocaine	2	10	Y
5	TC/TCN	Y	Resolved (27SEP2020)	NOT RELATED/OTHER: substance abuse	2	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.3 cm	87.5 kg	33.2 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
broken jaw repair surgery	Fracture treatment	1992	Past
Broken jaw	Jaw fracture	1992	Past
occasional migraines	Migraine	1995	Present
allergic rhinitis	Rhinitis allergic	2000	Present
Bilateral carpal tunnel syndrome	Carpal tunnel syndrome	2005	Past
Bilateral carpal tunnel release	Carpal tunnel decompression	2011	Past
menorrhagia	Menorrhagia	2015	Past
Reduction Mammoplasty (breast reduction)	Mammoplasty	DEC2018	Past
endometrial ablation	Endometrial ablation	DEC2019	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	10:48
2	BNT162b2	06OCT2020 (22)	09:32

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Appendicitis	Appendicitis	22OCT2020 (38)		23OCT2020 (39)	05:00	2	4	TCN
2	GENRL	Chills	Chills	06OCT2020 (22)	21:30	07OCT2020 (23)	08:00	2	1	N
3	GENRL	Injection site pain	Injection Site Pain	06OCT2020 (22)	13:00	07OCT2020 (23)		2	1	N
4	GENRL	Injection site pain	soreness at injection site	16SEP2020 (2)		17SEP2020 (3)		2	1	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (23OCT2020)	NOT RELATED/OTHER: Inflammation of Appendix, Unknown Cause	2	17	Y
2	N	Resolved (07OCT2020)	Study Treatment	2	1	N
3	N	Resolved (07OCT2020)	Study Treatment	2	1	N
4	N	Resolved (17SEP2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	27OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.96 cm	85.82 kg	29 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
environmental allergies	Hypersensitivity	1952	Present
seasonal allergies	Seasonal allergy	1952	Present
umbilical hernia	Umbilical hernia	1955	Past
Myopia	Myopia	JUN1962	Present
tonsillitis	Tonsillitis	JUN1962	Past
appendicitis	Appendicitis	JUN1968	Past
dyslipidemia	Dyslipidaemia	JUN1988	Present
hypertension	Hypertension	JUN1988	Present
inguinal hernia	Inguinal hernia	2011	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
basal cell carcinoma right shoulder	Basal cell carcinoma	2012	Past
actinic keratosis	Actinic keratosis	JUN2013	Present
plantar fasciitis in the right foot	Plantar fasciitis	JUN2017	Past
basal cell carcinoma on nose	Basal cell carcinoma	AUG2018	Past
gastro esophageal reflux disease	Gastrooesophageal reflux disease	JUN2019	Present
basal cell carcinoma on nose	Basal cell carcinoma	JUN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	15:54
2	BNT162b2	06OCT2020 (49)	14:30

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Atrial fibrillation	Arrhythmia atrial fibrillation	26AUG2020 (8)		27AUG2020 (9)		2	2	TC	Y
2	INV	Troponin increased	Elevated troponin	26AUG2020 (8)		26AUG2020 (8)		1	1	N	N

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Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (27AUG2020)	NOT RELATED/OTHER: medical records being reviewed not able to answer at this time.	1	8	Y
2	Resolved (26AUG2020)	NOT RELATED/OTHER: Unknown	1	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	02NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.83 cm	91 kg	33.8 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
postmenopausal	Postmenopause	2003	Present
Gastric Bypass	Gastric bypass	2007	Present
dyslipidemia	Dyslipidaemia	2010	Present
hypertension	Hypertension	2010	Present
type 2 diabetes	Type 2 diabetes mellitus	2010	Present
Lap Band procedure	Gastric banding	2012	Present
gastro esophageal reflux disease	Gastrooesophageal reflux disease	2015	Present
anxiety	Anxiety	2018	Present
Hernia repair	Hernia repair	26JUN2020	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	01SEP2020 (1)	10:03
2	Placebo	19OCT2020 (49)	09:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain upper	Epigastric Pain	07OCT2020 (37)	21:30	08OCT2020 (38)	17:30	2	3
2	GASTR	Chronic gastritis	Chronic Focally Active Gastritis	07OCT2020 (37)		ONGOING			2
3	EYE	Eye swelling	Swelling of eyes	17SEP2020 (17)		18SEP2020 (18)		2	2
4	GASTR	Lip swelling	Swelling of lip	17SEP2020 (17)		18SEP2020 (18)		2	2
5	SKIN	Urticaria	Hives (Urticaria)	17SEP2020 (17)		18SEP2020 (18)		2	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (08OCT2020)	NOT RELATED/OTHER: Gastric Pouch distention	1	37	Y
2	N	N	Yes	NOT RELATED/OTHER: Unknown	1	37	N
3	TC	N	Resolved (18SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	17	N
4	TC	N	Resolved (18SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	17	N
5	TC	N	Resolved (18SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	17	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	72	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	134.64 kg	40.2 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
type 2 diabetes	Type 2 diabetes mellitus	2003	Present
asthma Controlled	Asthma	2004	Present
seasonal allergies	Seasonal allergy	2005	Present
obesity	Obesity	2010	Present
dyslipidemia	Dyslipidaemia	MAY2010	Present
hypertension	Hypertension	SEP2010	Present
transient ischemic attack	Transient ischaemic attack	06DEC2013	Past
insomnia	Insomnia	2017	Present
coronary artery bypass graft	Coronary artery bypass	10JAN2020	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
coronary artery disease	Coronary artery disease	10JAN2020	Present
atrial fibrillation	Atrial fibrillation	06JUL2020	Present
insertion of intra-cardiac defibrillator	Implantable defibrillator insertion	06JUL2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15SEP2020 (1)	11:06
2	BNT162b2	06OCT2020 (22)	10:49

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Cardiac failure congestive	Congestive heart failure	01OCT2020 (17)	01:00	03OCT2020 (19)		3	2	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (03OCT2020)	NOT RELATED/OTHER: Progression of cardiovascular disease	1	17	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	03NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1993	26	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.8 cm	90.9 kg	27.2 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	1995	Present
Eczema	Eczema	1995	Present
Seasonal allergies	Seasonal allergy	1995	Present
Inguinal hernia	Inguinal hernia	1998	Past
Inguinal hernia repair	Inguinal hernia repair	1998	Past
Diabetes Type II	Type 2 diabetes mellitus	2011	Present
wisdom teeth removal	Wisdom teeth removal	2013	Past
Anxiety	Anxiety	2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25SEP2020 (1)	11:21
2	Placebo	10NOV2020 (47)	11:21

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Colon injury	colon injury	16OCT2020 (22)		23OCT2020 (29)		8	3
2	INJ&P	Road traffic accident	motor vehicle accident	16OCT2020 (22)		16OCT2020 (22)		1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (23OCT2020)	NOT RELATED/OTHER: Motor vehicle accident	1	22	Y
2	N	N	Resolved (16OCT2020)	NOT RELATED/OTHER: driving accident	1	22	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	65	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.5 cm	99.3 kg	33 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
congenital jaw misalignment	Congenital jaw malformation	(b) (6) 1954	Past
tonsillectomy	Tonsillectomy	1965	Past
tonsillitis	Tonsillitis	1965	Past
hepatitis B	Hepatitis B	1981	Past
migraines	Migraine	1985	Present
jaw surgery- fix misalignment	Jaw operation	2000	Past
mitral valve prolapse	Mitral valve prolapse	2005	Present
postmenopausal symptoms	Menopausal symptoms	2009	Present
seasonal allergies	Seasonal allergy	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
cartilage deterioration (both knees)	Cartilage injury	2011	Past
partial knee replacement (left)	Knee arthroplasty	2011	Past
partial knee replacement (right)	Knee arthroplasty	2013	Past
ankel surgery (right ankle)	Ankle operation	2017	Past
torn right ankle tendon	Tendon rupture	2017	Past
cataracts (bilateral)	Cataract	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07AUG2020 (1)	15:10
2	BNT162b2	28AUG2020 (22)	09:53

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Pulmonary embolism	Pulmonary Embolism	30OCT2020 (85)		07NOV2020 (93)		9	3

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Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (07NOV2020)	NOT RELATED/OTHER: HRT and prolonged immobilization	2	64	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	28SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1938	82	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	103.8 kg	32 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hepatitis A	Hepatitis A	1965	Past
Coronary stents Insertion (3)	Coronary arterial stent insertion	1995	Present
Post Traumatic Stress Disorder	Post-traumatic stress disorder	1995	Present
Diabetes mellitus Type 2	Type 2 diabetes mellitus	1995	Present
Hypercholesterolemia	Hypercholesterolaemia	1998	Present
Hypertension	Hypertension	2000	Present
hyperthyroidism	Hyperthyroidism	2009	Past
Hypothyroidism	Hypothyroidism	2009	Present
Thyroidectomy	Thyroidectomy	2009	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Eastern Equine Encephalitis	Encephalitis eastern equine	2010	Present
Coronary artery disease	Coronary artery disease	2013	Present
Sleep apnea	Sleep apnoea syndrome	2016	Present
Irritable Bowel Syndrome	Irritable bowel syndrome	2018	Present
Pacemaker Implant	Cardiac pacemaker insertion	23DEC2019	Past
Mild cellulitis (right arm)	Cellulitis	MAR2020	Present
insomnia	Insomnia	15JUL2020	Present
Pacemaker Explant	Cardiac pacemaker removal	24JUL2020	Past
Muscle strain (left arm)	Muscle strain	31JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	17:55
2	Placebo	27AUG2020 (21)	15:11

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Dizziness	Dizziness, secondary to Clonidine reaction	31AUG2020 (25)	16:00	02SEP2020 (27)		3	2	N	Y

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Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
2	METAB	Hypoglycaemia	Hypoglycemia	12AUG2020 (6)	12:00	12AUG2020 (6)	13:00	1	1	TCN	N
3	CARD	Tachyarrhythmia	Suspected tachy-arrythmia	08SEP2020 (33)		22SEP2020 (47)		15	3	TC	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (02SEP2020)	NOT RELATED/OTHER: unknown	2	5	Y
2	Resolved (12AUG2020)	NOT RELATED/OTHER: Hypoglycemia, on insulin, is type II diabetic	1	6	N
3	Resolved (22SEP2020)	NOT RELATED/OTHER: underlying cardiac condition likely requiring pacemaker	2	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	28SEP2020	
Withdrawn	FOLLOW-UP	28SEP2020	WITHDRAWAL BY SUBJECT

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.5 cm	84.6 kg	28.1 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	1986	Past
Osteoarthritis (left knee)	Osteoarthritis	2000	Past
Knee replacement (left)	Knee arthroplasty	2001	Past
Osteoarthritis (right knee)	Osteoarthritis	2018	Present
Atrial Septal Defect	Atrial septal defect	05NOV2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	12:08
2	BNT162b2	22SEP2020 (23)	14:26

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Dizziness	Dizziness	05NOV2020 (67)		06NOV2020 (68)		2	1
2	MUSC	Myalgia	post vaccination myalgia	31AUG2020 (1)	18:00	31AUG2020 (1)	23:00	1	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (06NOV2020)	NOT RELATED/OTHER: Atrial Septal Defect	2	45	Y
2	N	N	Resolved (31AUG2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Influenza vaccine 1 dose IM once for influenza prophylaxis	INFLUENZA VACCINE	13OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.5 cm	77.5 kg	25.7 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1954	Past
Tonsillitis	Tonsillitis	1954	Past
Inguinal Hernia Repair	Inguinal hernia repair	1986	Past
Hypertension	Hypertension	2009	Present
Benign prostatic Hyperplasia	Benign prostatic hyperplasia	2010	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Angina	Angina pectoris	SEP2010	Present
Coronary Stent placement	Coronary arterial stent insertion	SEP2010	Present
Coronary Artery disease	Coronary artery disease	SEP2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Myocardial infarction	Myocardial infarction	SEP2010	Past
Erectile Dysfunction	Erectile dysfunction	2011	Present
Osteoarthritis	Osteoarthritis	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	11:46
2	BNT162b2	21SEP2020 (20)	09:22

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Bladder cancer	Bladder Cancer	02NOV2020 (62)		ONGOING		
2	GENRL	Injection site pain	Injection site pain right arm	21SEP2020 (20)	18:00	22SEP2020 (21)	08:00	2
3	GENRL	Injection site pain	injection site pain right arm	02SEP2020 (1)	16:00	03SEP2020 (2)	12:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Yes	NOT RELATED/OTHER: cancer	2	43	Y

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Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	1	N	N	Resolved (22SEP2020)	Study Treatment	2	1	N
3	1	N	N	Resolved (03SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	64	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	115.2 kg	33.3 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Lichen Planus	Lichen planus	01JAN2009	Present
Hypertension	Hypertension	01FEB2014	Present
Erectile dysfunction	Erectile dysfunction	01JAN2015	Present
Eczema	Eczema	01OCT2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	16:16
2	BNT162b2	24SEP2020 (21)	09:10

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1			shortness of breath	13NOV2020 (71)		ONGOING			2
2	GENRL	Fatigue	Fatigue	24SEP2020 (21)	16:00	25SEP2020 (22)	14:00	2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/OTHER: possible viral illness	2	51	Y
2	N	N	Resolved (25SEP2020)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.96 cm	96.36 kg	32.5 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DIABETES MELLITUS TYPE 2	Type 2 diabetes mellitus	1990	Present
ANXIETY	Anxiety	2017	Present
CHRONIC KIDNEY DISEASE	Chronic kidney disease	2017	Present
DEPRESSION	Depression	2017	Present
DIABETIC NEUROPATHY	Diabetic neuropathy	2017	Present
DRUG ABUSE COCAINE	Drug abuse	2017	Past
HYPERLIPIDEMIA	Hyperlipidaemia	2017	Present
HYPERTENSION	Hypertension	2017	Present
INSOMIA	Insomnia	2017	Present

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Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
SLEEP APNEA	Sleep apnoea syndrome	2017	Present
CONGESTIVE HEART FAILURE	Cardiac failure congestive	04JUL2017	Present
CORONATY ARTERY DISEASE	Coronary artery disease	04JUL2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	12:32
2	Placebo	10SEP2020 (24)	11:10

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INV	Hepatic enzyme increased	Elevated Liver Enzymes	21SEP2020 (35)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: UNKNOWN	2	12	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	100.18 kg	29.9 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DEPRESSION	Depression	2002	Present
TONSILLECTOMY	Tonsillectomy	2002	Past
UMBILICAL HERNIA	Umbilical hernia	2002	Past
HYPERLIPIDEMIA	Hyperlipidaemia	2014	Present
HYPERTENSION	Hypertension	2014	Present
ANXIETY	Anxiety	2015	Present
TESTOSTERONE DEFICIENCY	Androgen deficiency	2017	Present
Insomnia	Insomnia	2017	Present
Intermittent lower back pain	Back pain	AUG2019	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Car accident	Road traffic accident	AUG2019	Past
HERNIATED C5-C7 DISC	Intervertebral disc protrusion	FEB2020	Past
C5-C7 FUSION	Spinal fusion surgery	FEB2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	13:14
2	Placebo	09SEP2020 (22)	13:26

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Diplegia	Bilateral Lower extremity paralysis	04OCT2020 (47)	09:00	05OCT2020 (48)		2	3	N	Y
2	VASC	Hypertension	worsening of hypertension	14SEP2020 (27)		ONGOING			1	TC	N
3	METAB	Hypokalaemia	HYPOKALEMIA	SEP2020 ()		SEP2020 ()			3	TC	Y

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Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (05OCT2020)	NOT RELATED/OTHER: unknown	2	26	Y
2	Yes	NOT RELATED/OTHER: past medical history	2	6	N
3	Resolved (SEP2020)	NOT RELATED/OTHER: PERSONAL ILLNESS, possibly related to con med amlodipine			Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	78	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	99.09 kg	31.3 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Atrial Fibrillation	Atrial fibrillation	09APR2018	Present
BPH	Benign prostatic hyperplasia	09APR2018	Present
Gout	Gout	09APR2018	Present
Hyperlipidemia	Hyperlipidaemia	09APR2018	Present
Hypertension	Hypertension	09APR2018	Present
Diabetes Mellitus Type II	Type 2 diabetes mellitus	09APR2018	Present
Transient Cerebral ischemia	Transient ischaemic attack	09JUL2019	Past
depressive Disorders	Depression	20NOV2019	Present
Obstructive Sleep Apnea	Sleep apnoea syndrome	20NOV2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	15:50
2	BNT162b2	09SEP2020 (21)	09:05

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Pneumonia	Pneumonia	20SEP2020 (32)		05OCT2020 (47)	11:00	16	3	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (05OCT2020)	NOT RELATED/OTHER: Pt contracted pneumonia from somewhere	2	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1943	76	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	74.55 kg	22.9 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Impotence	Erectile dysfunction	03APR2000	Present
Essential Hypertension	Essential hypertension	03APR2018	Present
Mechanical Heart valve Replacement	Heart valve replacement	03APR2018	Past
Hyperlipidemia	Hyperlipidaemia	03APR2018	Present
Chronic Back Pain1	Back pain	01OCT2018	Present
Neuropathy	Neuropathy peripheral	01OCT2018	Present
Lumbar Radiculopathy	Lumbar radiculopathy	04FEB2019	Present
Gout	Gout	15APR2019	Present
Osteoarthritis	Osteoarthritis	29JUN2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	11:48
2	Placebo	15SEP2020 (25)	13:37

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Encephalopathy	Acute encephalopathy	18OCT2020 (58)	21:40	ONGOING			3
2	SURG	Hospitalisation	Hospitalization not otherwise specified.	13NOV2020 (84)		ONGOING			3
3	INFEC	Urinary tract infection	urinary tract infection	19SEP2020 (29)		01NOV2020 (72)		44	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/OTHER: COVID 19 and UTI and OPiod use	2	34	Y
2	N	Y	Yes	NOT RELATED/OTHER: unknown at this time	2	60	Y
3	TC	N	Resolved (01NOV2020)	NOT RELATED/OTHER: unknown	2	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	89.09 kg	28.9 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Coronary arteriosclerosis	Arteriosclerosis coronary artery	12JUN2018	Present
Essential Hypertension	Essential hypertension	12JUN2018	Present
Hyperlipidemia	Hyperlipidaemia	12JUN2018	Present
Type II Diabetes	Type 2 diabetes mellitus	12JUN2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	12:48
2	BNT162b2	14SEP2020 (22)	11:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute myocardial infarction	Non-STEMI	15SEP2020 (23)	12:33	15SEP2020 (23)	12:33	1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (15SEP2020)	NOT RELATED/OTHER: Three vessel Disease	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	61.36 kg	22.5 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Pulmonary Fibrosis	Pulmonary fibrosis	DEC2015	Present
ADHD	Attention deficit hyperactivity disorder	23MAR2018	Present
COPD	Chronic obstructive pulmonary disease	23MAR2018	Present
Fibromyalgia	Fibromyalgia	23MAR2018	Present
Hyperlipidemia	Hyperlipidaemia	23MAR2018	Present
Hypertension	Hypertension	23MAR2018	Present
Degenerative Lumbar disc	Intervertebral disc degeneration	23MAR2018	Present
Vit D deficiency	Vitamin D deficiency	23MAR2018	Present
Chronic depression	Depression	22APR2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Peripheral Vascular Disease	Peripheral vascular disorder	18FEB2020	Present
Anxiety	Anxiety	23MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	28AUG2020 (1)	13:35
2	BNT162b2	17SEP2020 (21)	14:03

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Acute kidney injury	Acute kidney injury	22OCT2020 (56)	23:57	25OCT2020 (59)	11:48	4	3
2	NERV	Uraemic encephalopathy	Uremic encephalopathy	22OCT2020 (56)	23:58	25OCT2020 (59)	11:48	4	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (25OCT2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	36	Y
2	TC	Y	Resolved (25OCT2020)	NOT RELATED/OTHER: uremic encaphalopathy due to AKI.	2	36	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1935	84	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	101.36 kg	36 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Angioplasty	Angioplasty	01OCT2003	Past
Right Knee Replacement	Knee arthroplasty	31MAY2005	Past
Right Rotator Cuff Repair	Rotator cuff repair	30NOV2006	Past
Cardiac Stent Insertion	Coronary arterial stent insertion	01MAY2008	Past
Obstructive Sleep Apnea	Sleep apnoea syndrome	15DEC2008	Present
Bladder stone removal	Bladder calculus removal	21APR2011	Past
Kidney stone removal	Renal stone removal	06JUN2011	Past
Appendectomy	Appendicectomy	19AUG2011	Past
Left Rotator Cuff repair	Rotator cuff repair	05OCT2011	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bladder Cancer	Bladder cancer	01MAY2012	Past
HEART CATHETERIZATION	Catheterisation cardiac	06FEB2013	Past
Cataract removal	Cataract operation	2014	Past
Neuropathy	Neuropathy peripheral	2015	Present
Hyperlipidemia	Hyperlipidaemia	13JUL2015	Present
Hypertension	Hypertension	15DEC2015	Present
Diabetes Mellitus Type II	Type 2 diabetes mellitus	15DEC2015	Present
Left Knee Replacement	Knee arthroplasty	26OCT2016	Past
Depression	Depression	26JUN2018	Present
Hypothyroidism	Hypothyroidism	29JAN2019	Present
GERD	Gastrooesophageal reflux disease	25MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	16:15
2	BNT162b2	23SEP2020 (23)	10:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Pneumonia	Pneumonia	07OCT2020 (37)		ONGOING			3

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Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: Pt contracted pneumonia from unknown source	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.69 cm	86.82 kg	29.7 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1980	Present
Myocardial Infarction	Myocardial infarction	1996	Past
A-Fib	Atrial fibrillation	2016	Present
COPD	Chronic obstructive pulmonary disease	2016	Present
Cronary Artery Disease	Coronary artery disease	2016	Present
Depression	Depression	2016	Present
Hyperlipidemia	Hyperlipidaemia	2016	Present
Hypertension	Hypertension	FEB2016	Present
Type 2 Diabetes	Type 2 diabetes mellitus	2017	Present
CHF	Cardiac failure congestive	2018	Present
GERD	Gastrooesophageal reflux disease	03AUG2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	10:41
2	Placebo	24SEP2020 (35)	09:40

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Angina unstable	Unstable Angina Pectoris Moderate	04OCT2020 (45)		05OCT2020 (46)		2	1
2	CARD	Cardiac failure congestive	Diastolic Congestive Heart Failure with acute exacerbation	07OCT2020 (48)		09OCT2020 (50)		3	1
3	GENRL	Chest pain	ChestPain	07OCT2020 (48)	19:30	09OCT2020 (50)	12:00	3	1
4	RESP	Chronic obstructive pulmonary disease	COPD with acute exacerbation	07OCT2020 (48)		09OCT2020 (50)		3	1
5	NERV	Dizziness	Dizziness	07OCT2020 (48)		07OCT2020 (48)		1	1
6	RESP	Dyspnoea	Shortness of Breath	01OCT2020 (42)		07OCT2020 (48)		7	1
7	INJ&P	Fall	fall	07OCT2020 (48)		07OCT2020 (48)		1	1
8	INFEC	Pneumonia	Community Acquired Pneumonia	07OCT2020 (48)		09OCT2020 (50)		3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (05OCT2020)	NOT RELATED/OTHER: unknown	2	11	N

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	N	N	Resolved (09OCT2020)	NOT RELATED/OTHER: unknown	2	14	N
3	TC/TCN	Y	Resolved (09OCT2020)	NOT RELATED/OTHER: Community Acquired Pneumonia	2	14	Y
4	TC	N	Resolved (09OCT2020)	NOT RELATED/OTHER: COPD	2	14	N
5	TC	N	Resolved (07OCT2020)	NOT RELATED/OTHER: Community Acquired Pneumonia	2	14	N
6	N	N	Resolved (07OCT2020)	NOT RELATED/OTHER: Pneomonia	2	8	N
7	TC	N	Resolved (07OCT2020)	NOT RELATED/OTHER: Community Acquired Pneumonia	2	14	N
8	N	Y	Resolved (09OCT2020)	NOT RELATED/OTHER: uknown	2	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flu vaccine	INFLUENZA VACCINE	09SEP2020

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.45 cm	109.36 kg	37.1 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
TUBAL LIGATION	Female sterilisation	2000	Past
HYSTERECTOMY	Hysterectomy	2000	Past
MENORRHAGIA	Menorrhagia	2000	Past
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2015	Present
SEASONAL ALLERGIES	Seasonal allergy	2018	Present
INSOMNIA	Insomnia	2019	Present
DEPRESSION	Depression	JAN2020	Present
CHRONIC RIGHT UPPER QUADRANT PAIN	Abdominal pain upper	MAR2020	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05AUG2020 (1)	11:28
2	BNT162b2	26AUG2020 (22)	14:05

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholelithiasis	CHOLELITHIASIS	11SEP2020 (38)		15SEP2020 (42)		5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (15SEP2020)	NOT RELATED/OTHER: UNKNOWN	2	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	23SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	43	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	133.82 kg	46.1 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OVERWEIGHT	Overweight	2010	Present
TRAUMATIC RIGHT ANKLE FRACTURE	Ankle fracture	2017	Past
RIGHT ANKLE REPAIR	Ankle operation	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	06AUG2020 (1)	15:01
2	Placebo	27AUG2020 (22)	07:48

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Anaemia	ANEMIA	09NOV2020 (96)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/TCN	Y	Yes	NOT RELATED/OTHER: UNKNOWN	2	75	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	06AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	83.64 kg	33.7 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Appendectomy	Appendicectomy	JAN1962	Past
Appendicitis	Appendicitis	JAN1962	Past
Tubal Ligation	Female sterilisation	JAN1988	Past
Depression	Depression	JAN1995	Present
Carpel Tunnel Syndrome, Bi-lateral	Carpal tunnel syndrome	JAN1997	Past
Diverticulosis	Diverticulum	JAN1998	Present
Hemorrhoids	Haemorrhoids	JAN1998	Present
Hypertension	Hypertension	JAN2000	Present
Obesity	Obesity	JAN2000	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis, Hip, Hands	Osteoarthritis	JAN2000	Present
Hand Surgery, Bi-lateral Thumb	Limb operation	JAN2002	Past
Hand Surgery, Bi-lateral Thumb	Limb operation	JAN2006	Past
Hypercholesterolemia	Hypercholesterolaemia	JAN2010	Present
HYPERTRIGLYCERIDEMIA	Hypertriglyceridaemia	JAN2010	Present
Deep Vein Thrombosis	Deep vein thrombosis	JAN2014	Present
Hot Flashes	Hot flush	JAN2017	Present
PTSD	Post-traumatic stress disorder	JUN2018	Present
Anxiety	Anxiety	01JUN2018	Present
Seasonal Allergies	Seasonal allergy	01AUG2019	Present
Cataract Surgery	Cataract operation	OCT2019	Past
Cystocele	Cystocele	OCT2019	Present
Rectocele	Rectocele	OCT2019	Present
Colonoscopy	Colonoscopy	JAN2020	Present
Polyp removal	Polypectomy	JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03AUG2020 (1)	11:00
2	BNT162b2	23AUG2020 (21)	10:18

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	RESP	Cough	COUGH	20AUG2020 (18)	08:00	04SEP2020 (33)		16	1	N
2	INFEC	Diverticulitis	Diverticulitis flair-up	08NOV2020 (98)	18:00	13NOV2020 (103)		6	4	TC

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (04SEP2020)	NOT RELATED/OTHER: POST NASAL DRIP	1	18	N
2	Y	Resolved (13NOV2020)	NOT RELATED/OTHER: Previous medical history of diverticulosis	2	78	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154.94 cm	111.82 kg	46.5 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OSTEOARTHRITIS BILATERAL KNEES	Osteoarthritis	2000	Present
Anxiety	Anxiety	JAN2010	Present
Obesity	Obesity	2015	Present
Postmenopausal	Postmenopause	2017	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	15:51
2	Placebo	24AUG2020 (21)	11:32

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Deep vein thrombosis	Deep Vein Thrombosis	07SEP2020 (35)		ONGOING			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/OTHER: Right Total Knee Replacement on 31 Aug 2020	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	21SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	27	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	90.91 kg	27.1 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RECONSTRUCTIVE RIGHT EAR SURGERY	Otoplasty	01JAN2013	Past
SEASONAL ALLERGIES	Seasonal allergy	2015	Present
BILATERAL LASIK SURGERY	Keratomileusis	01JAN2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	13:15
2	BNT162b2	04SEP2020 (25)	14:18

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Appendicitis	ACUTE APPENDICITIS	17AUG2020 (7)		02SEP2020 (23)		17	4	TC	Y
2	INFEC	Peritoneal abscess	Peritoneal Abscess	17AUG2020 (7)		02SEP2020 (23)		17	4	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (02SEP2020)	NOT RELATED/OTHER: ACUTE APPENDICITIS WITH PERITONEAL ABSCESS	1	7	Y
2	Resolved (02SEP2020)	NOT RELATED/OTHER: Acute appendicitis with peritoneal abscess	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	62	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	59.91 kg	20 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
MIGRAINE HEADACHES	Migraine	01JAN1989	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	01JAN2005	Present
BREAST CANCER	Breast cancer	01JAN2012	Past
ANXIETY	Anxiety	01JAN2015	Present
DEPRESSION	Depression	01JAN2015	Present
HYSTERECTOMY	Hysterectomy	01JAN2019	Past
POSTMENOPAUSAL	Postmenopause	01JAN2019	Present
OSTEOPOROSIS	Osteoporosis	01JAN2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	09:35
2	Placebo	09SEP2020 (20)	13:11

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Complicated appendicitis	Acute appendicitis with necrosis	30SEP2020 (41)	23:00	02OCT2020 (43)	11:00	3	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (02OCT2020)	NOT RELATED/OTHER: Infection of appendix	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	82.27 kg	30.1 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
VASECTOMY	Vasectomy	1997	Past
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2010	Present
HYPOTHYROIDISM	Hypothyroidism	2010	Present
OSTEOARTHRITIS-RIGHT KNEE	Osteoarthritis	2014	Present
SLEEP APNEA	Sleep apnoea syndrome	2015	Present
ROSACEA	Rosacea	2017	Present
ENLARGED PROSTATE	Prostatomegaly	2018	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	13:21
2	BNT162b2	22SEP2020 (22)	14:40

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Deep vein thrombosis	Deep Vein Thrombosis (Right Leg)	20OCT2020 (50)		ONGOING			3
2	MUSC	Osteoarthritis	Worsening osteoarthritis of the right knee	14OCT2020 (44)	09:00	15OCT2020 (45)		2	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: Knee surgery (right)	2	29	N
2	TC/TCN	Y	Resolved (15OCT2020)	NOT RELATED/OTHER: Previous medical history	2	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	23OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	82.73 kg	29.4 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
FIBROMYALGIA	Fibromyalgia	1990	Present
ALLERGY TO AUGMENTIN	Drug hypersensitivity	1995	Present
ALLERGY TO KEFLEX	Drug hypersensitivity	1995	Present
ALLERGY TO BIAXIN	Drug hypersensitivity	2005	Present
ALLERGY TO LATEX	Rubber sensitivity	2005	Present
HYSTERECTOMY	Hysterectomy	2006	Past
POSTMENOPAUSAL	Postmenopause	2006	Present
ALLERGY TO SEPTRA	Drug hypersensitivity	2008	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Headaches	Headache	2010	Present
Hemiplegic Migraine	Hemiplegic migraine	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	15:07
2	Placebo	28SEP2020 (21)	08:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Hemiplegic migraine	Hemiplegic Migraine	20OCT2020 (43)		ONGOING			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Yes	NOT RELATED/OTHER: Related to subjects history of headaches	2	23	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	111.36 kg	40.8 kg/m2	05OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HEPATITIS C	Hepatitis C	2005	Past
DEPRESION	Depression	2010	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2010	Present
HYPERTENSION	Hypertension	2010	Present
ALLERGIES SEASONAL	Seasonal allergy	2010	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05OCT2020 (1)	15:51
2	BNT162b2	24OCT2020 (20)	14:44

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	RESP	Dyspnoea	Shortness of breath	06NOV2020 (33)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		4	TC	Y	Yes	NOT RELATED/OTHER: Inflammation	2	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05OCT2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	95.25 kg	33.3 kg/m2	04AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
HYPERTENSION	Hypertension	2000	Present
GASTROESOPHAGEAL REFLUX DISEASE	Gastrooesophageal reflux disease	2005	Present
HYPERCHOLESTEROLEMIA	Hypercholesterolaemia	2015	Present
NEPHROLITHIASIS	Nephrolithiasis	JAN2019	Present
SLEEP DISTURBANCE	Sleep disorder	JAN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04AUG2020 (1)	12:37
2	Placebo	25AUG2020 (22)	10:51

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	METAB	Type 2 diabetes mellitus	Diabetes Type 2	12NOV2020 (101)		ONGOING			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Yes	NOT RELATED/OTHER: diabetes mellitus type 2 uncontrolled	2	80	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04AUG2020	
Completed	VACCINATION	23SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	57.55 kg	21.7 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to codeine	Drug hypersensitivity	1972	Present
Postmenopausal	Postmenopause	1987	Present
Hypercholesterolemia	Hypercholesterolaemia	2010	Present
Farsighted	Hypermetropia	2010	Present
Hypertension	Hypertension	2010	Present
Hypothyroidism	Hypothyroidism	2010	Present
Melanoma (left forearm)	Malignant melanoma	2010	Past
Mohs surgery	Micrographic skin surgery	2010	Past
Muscle spasms	Muscle spasms	2017	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11AUG2020 (1)	13:31
2	BNT162b2	01SEP2020 (22)	12:34

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	PSYCH	Mental disorder	Undiagnosed Mental Disorder (not otherwise specified)	25SEP2020 (46)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: mental instability	2	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11AUG2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	75.91 kg	26.2 kg/m2	14AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Overweight	Overweight	1970	Present
Hypertension	Hypertension	1997	Present
Kidney stones	Nephrolithiasis	1997	Past
Tubal ligation	Female sterilisation	1998	Past
Diverticulosis	Diverticulum	2010	Present
Cholecystectomy	Cholecystectomy	2012	Past
Gallstones	Cholelithiasis	2012	Past
Disseminated porokeratosis	Porokeratosis	2013	Present
Sleep apnea	Sleep apnoea syndrome	2013	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Carpal tunnel syndrome (right)	Carpal tunnel syndrome	2014	Past
Farsighted	Hypermetropia	2015	Present
Uterine ablation	Endometrial ablation	2016	Past
Post-menopause	Postmenopause	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14AUG2020 (1)	13:26
2	BNT162b2	04SEP2020 (22)	16:56

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Pyelonephritis	Pyelonephritis	28SEP2020 (46)		02OCT2020 (50)		5	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (02OCT2020)	NOT RELATED/OTHER: kidney stones/nephrolithiasis	2	25	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	American Indian or Alaska	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161.29 cm	66.73 kg	25.6 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	1987	Present
Back Pain	Back pain	2000	Present
Vitamin D deficiency	Vitamin D deficiency	2010	Present
Farsighted	Hypermetropia	2012	Present
Low libido	Libido decreased	2012	Present
Seasonal allergies	Seasonal allergy	2017	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	15:18
2	BNT162b2	24SEP2020 (38)	11:38

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Subarachnoid haemorrhage	Subarachnoid hemorrhage	26AUG2020 (9)		03SEP2020 (17)		9

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	Y	Resolved (03SEP2020)	NOT RELATED/OTHER: unknown	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1942	77	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	70.55 kg	22.6 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Alcohol use	Alcohol use		Present
High cholesterol	Blood cholesterol increased	2010	Present
Indigestion (acid)	Dyspepsia	2010	Present
Hypertension	Hypertension	2010	Present
Type II Diabetes Mellitus	Type 2 diabetes mellitus	2010	Present
Transient ischemic attack	Transient ischaemic attack	2016	Past
Transient ischemic attack	Transient ischaemic attack	2017	Past
Low libido	Libido decreased	2018	Present
Constipation	Constipation	2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15OCT2020 (1)	09:58
2	Placebo	05NOV2020 (22)	09:11

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Pancreatitis acute	Acute Pancreatitis	19OCT2020 (5)		21OCT2020 (7)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (21OCT2020)	NOT RELATED/OTHER: Alcohol use	1	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15OCT2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.5 cm	127.7 kg	37.1 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Neuropathy	Neuropathy peripheral	JAN1986	Present
Type 2 Diabetes Mellitus	Type 2 diabetes mellitus	01JAN1986	Present
Trama Right Leg	Limb injury	01JAN2005	Past
Trauma Left Leg	Limb injury	01JAN2005	Past
Anxiety	Anxiety	01JAN2010	Present
Amputed Right Leg	Leg amputation	01NOV2012	Past
Depression	Depression	01JAN2013	Present
Asthma	Asthma	OCT2015	Present
Recurrent Methicillin-resistant Staphylococcus aureus Infections	Staphylococcal infection	JAN2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	03NOV2017	Present
Amputed Left Leg	Leg amputation	01JAN2018	Past
Hyperlipidemia	Hyperlipidaemia	14NOV2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	15:03
2	BNT162b2	30SEP2020 (38)	09:15

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Acute kidney injury	acute kidney injury	12SEP2020 (20)		ONGOING		
2	CARD	Atrial fibrillation	Atrial fibrillation	14SEP2020 (22)	10:00	ONGOING		
3	GENRL	Chest pain	chest pain	14SEP2020 (22)	10:00	14SEP2020 (22)	11:00	1
4	CARD	Left ventricular hypertrophy	Left Ventricular Hypertrophy	14SEP2020 (22)	10:00	ONGOING		
5	CARD	Mitral valve incompetence	mitral valve regurgitation	14SEP2020 (22)	10:00	ONGOING		
6	MUSC	Pain in extremity	bilateral hand pain	12SEP2020 (20)		13SEP2020 (21)		2
7	RESP	Pulmonary hypertension	Pulmonary Hypertension	14SEP2020 (22)	10:00	ONGOING		
8	INJ&P	Skin injury	skin avulsion, left finger	12SEP2020 (20)		12SEP2020 (20)		1

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Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
9	INFEC	Staphylococcal infection	MRSA infection Right Stump	12SEP2020 (20)	08:00	08OCT2020 (46)		27
10	CARD	Tricuspid valve incompetence	Tricuspid regurgitation	14SEP2020 (22)	10:00	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Yes	NOT RELATED/OTHER: Hypertension	1	20	N
2	2	N	N	Yes	NOT RELATED/OTHER: Hypertension	1	22	N
3	2	N	N	Resolved (14SEP2020)	NOT RELATED/OTHER: Hypertension	1	22	N
4	1	N	N	Yes	NOT RELATED/OTHER: hypertension	1	22	N
5	1	N	N	Yes	NOT RELATED/OTHER: hypertension	1	22	N
6	1	N	N	Resolved (13SEP2020)	NOT RELATED/OTHER: Musculoskeletal	1	20	N
7	1	N	N	Yes	NOT RELATED/OTHER: hypertension	1	22	N
8	2	N	N	Resolved (12SEP2020)	NOT RELATED/OTHER: Musculoskeletal	1	20	N
9	2	TC	Y	Resolved (08OCT2020)	NOT RELATED/OTHER: Infection	1	20	Y
10	1	N	N	Yes	NOT RELATED/OTHER: Hypertension	1	22	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Pneumonia vaccine	PNEUMOCOCCAL VACCINE	26AUG2020
Influenza Vaccine	INFLUENZA VACCINE	23SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	82.36 kg	26.8 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Shoulder Pain	Arthralgia	2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	12:48
2	Placebo	18SEP2020 (22)	11:12

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Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Thrombocytopenia	Thrombocytopenia	27OCT2020 (61)		11NOV2020 (76)		16	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (11NOV2020)	NOT RELATED/OTHER: Unknown at this time	2	40	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1999	20	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
151.13 cm	91.73 kg	40.1 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2019	Present
Abdominal Pain undiagonised origin	Abdominal pain	AUG2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	11:54
2	BNT162b2	22SEP2020 (23)	14:40

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	HEPAT	Bile duct stone	Choledocholithiasis	13SEP2020 (14)	19:00	19SEP2020 (20)	01:01	7	3	TC/TCN	Y
2	GASTR	Obstructive pancreatitis	Gall Stone Pancreatitis	13SEP2020 (14)		18SEP2020 (19)		6	3	TC/TCN	Y
3	CARD	Sinus arrhythmia	Sinus Arythima	14SEP2020 (15)	00:00	ONGOING			1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (19SEP2020)	NOT RELATED/OTHER: Patient had underlying, undiagnosed condition	1	14	Y
2	Resolved (18SEP2020)	NOT RELATED/OTHER: Undiagnosed preexisiting condition	1	14	Y
3	Yes	NOT RELATED/OTHER: This was likely there before and just undiagnosed	1	15	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
194.56 cm	122.36 kg	32.3 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
FISH ALLERGY	Food allergy	1979	Present
ALCOHOLISM	Alcoholism	2005	Past
BIPOLAR DISORDER	Bipolar disorder	2016	Present
DEPRESSION	Depression	2016	Present
HYPERTENSION	Hypertension	2016	Present
SCHIZOPHRENIA	Schizophrenia	2016	Present
ANXIETY	Anxiety	2017	Present
INSOMNIA	Insomnia	2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
CONSTIPATION	Constipation	2018	Present
DIABETES MELLITUS TYPE II	Type 2 diabetes mellitus	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	16:02
2	Placebo	10SEP2020 (22)	13:12

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	RENAL	Acute kidney injury	ACUTE KIDNEY INJURY	26AUG2020 (7)		30AUG2020 (11)		5	1	TC	N
2	MUSC	Musculoskeletal stiffness	NECK STIFFNESS	21SEP2020 (33)	08:00	ONGOING			1	N	N
3	MUSC	Pain in extremity	ARM SORENESS, LEFT	22SEP2020 (34)	08:00	02OCT2020 (44)		11	2	N	N
4	MUSC	Rhabdomyolysis	RHABDOMYOLYSIS	26AUG2020 (7)		30AUG2020 (11)		5	1	TC	N

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Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
5	PSYCH	Suicidal ideation	Suicidal ideation	27AUG2020 (8)		30AUG2020 (11)		4	4	TC	Y
6	NERV	Syncope	Syncopal Episode	26AUG2020 (7)		30AUG2020 (11)		5	4	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (30AUG2020)	NOT RELATED/OTHER: HEAT RELATED EVENT	1	7	N
2	Yes	NOT RELATED/OTHER: ETIOLOGY UNKNOWN PER INVESTIGATOR	2	12	N
3	Resolved (02OCT2020)	NOT RELATED/OTHER: ETIOLOGY NOT KNOWN PER INVESTIGATOR	2	13	N
4	Resolved (30AUG2020)	NOT RELATED/OTHER: HEAT RELATED EVENT	1	7	N
5	Resolved (30AUG2020)	NOT RELATED/OTHER: Per participant: "due to being in the hospital"	1	8	Y
6	Resolved (30AUG2020)	NOT RELATED/OTHER: Due to heat, acute kidney injury, rhabdomyolysis	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
INFLUENZA VACCINE	INFLUENZA VACCINE	14SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	91.3 kg	35.7 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PSORIASIS	Psoriasis	1957	Present
ALLERGY TO IODINE	Iodine allergy	1976	Present
BRONCHIAL ASTHMA	Asthma	1990	Present
ENVIRONMENTAL ALLERGIES	Hypersensitivity	1990	Present
HYPERTENSION	Hypertension	1990	Present
OSTEOARTHRITIS BILATERAL KNEE, HIP	Osteoarthritis	1990	Present
OSTEOARTHRITIS SPINE	Spinal osteoarthritis	1990	Present
HYPERLIPIDEMIA	Hyperlipidaemia	2010	Present
CORONARY ARTERY DISEASE	Coronary artery disease	2011	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	14:15
2	Placebo	08SEP2020 (23)	14:15

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1			bilateral pulmonary embolism	11NOV2020 (87)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: pulmonary embolism	2	65	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.3 cm	52.9 kg	20.1 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
migraines	Migraine	1977	Present
dermatitis	Dermatitis	1990	Present
metamucil allergy	Drug hypersensitivity	1990	Present
hypertension	Hypertension	2009	Present
hypothyroidism	Hypothyroidism	2009	Present
post menopausal	Postmenopause	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	15:32
2	BNT162b2	10SEP2020 (24)	12:18

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Diverticulitis	Sigmoid diverticulitis	04SEP2020 (18)		18SEP2020 (32)	00:00	15	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (18SEP2020)	NOT RELATED/OTHER: Sigmoid diverticulosis	1	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.6 cm	80.5 kg	30.4 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
DEPRESSION	Depression	1990	Present
sarcoidosis	Sarcoidosis	2010	Present
HYPERLIPIDEMIA	Hyperlipidaemia	2014	Present
SEASONAL ALLERGIES	Seasonal allergy	2018	Present
RHINITIS	Rhinitis	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	13:26
2	Placebo	11SEP2020 (23)	11:37

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	METAB	Gout	GOUT RIGHT FOOT	06OCT2020 (48)	00:00	ONGOING			1
2	MUSC	Musculoskeletal chest pain	chest wall pain	14SEP2020 (26)	10:30	03NOV2020 (76)		51	2

Adverse Events						
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	26	N
2	TC	Y	Resolved (03NOV2020)	NOT RELATED/OTHER: unknown at this time	2	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	16OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	86.36 kg	26.5 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
High Cholesterol	Blood cholesterol increased	2001	Present
Vasectomy	Vasectomy	2001	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	2004	Present
Lower back pain	Back pain	2009	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	14:53
2	BNT162b2	16SEP2020 (22)	08:58

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute myocardial infarction	ST elevation myocardial infarction	27SEP2020 (33)		13OCT2020 (49)		17	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (13OCT2020)	NOT RELATED/OTHER: related to cardiovascular risk	2	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	70	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	77.1 kg	31.3 kg/m2	30JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
urinary Tract Infection - Recurrent	Urinary tract infection	1951	Present
Bronchitis - Recurrent	Bronchitis	1960	Present
Seasonal Allergies	Seasonal allergy	1960	Present
Myopia	Myopia	1962	Present
Migraines	Migraine	1980	Present
Allergy to Non-Steroidal Anti-Inflammatory drugs	Drug hypersensitivity	1990	Present
hypothyroidism	Hypothyroidism	1992	Present
Hypertension	Hypertension	1993	Present
Asthma	Asthma	1995	Present

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Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Insomnia	Insomnia	1995	Present
Hyperlipidemia	Hyperlipidaemia	1998	Present
postmenopausal	Postmenopause	2000	Present
Uterine polyps	Uterine polyp	2002	Past
Hysterectomy	Hysterectomy	2005	Past
osteoarthritis - Bilateral Hips	Osteoarthritis	2008	Present
osteoarthritis - Generalized	Osteoarthritis	2008	Present
Osteoarthritis - Left Shoulder	Osteoarthritis	2018	Present
Hearing Loss Bilateral	Deafness bilateral	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30JUL2020 (1)	17:52
2	BNT162b2	18AUG2020 (20)	10:39

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	RESP	Asthma	worsening of asthma	01OCT2020 (64)		ONGOING	
2	NEOPL	Invasive ductal breast carcinoma	Malignant invasive ductal carcinoma left breast	05NOV2020 (99)	11:55	ONGOING	

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Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		1	TC	N	Yes	NOT RELATED/OTHER: allergy	2	45	N
2		3	N	Y	Yes	NOT RELATED/OTHER: malignancy	2	80	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Influenza vaccination	INFLUENZA VACCINE	08SEP2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	15SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1941	79	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	90.64 kg	29 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1953	Past
Tonsillitis	Tonsillitis	1953	Past
Appendectomy	Appendicectomy	1956	Past
Appendicitis	Appendicitis	1956	Past
Vasectomy	Vasectomy	1974	Past
Anxiety	Anxiety	1995	Present
Diabetes Type 2	Type 2 diabetes mellitus	2005	Present
Prostate Cancer, malignant	Prostate cancer	2008	Past
Prostectomy	Prostatectomy	2008	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
elevated cholesterol	Blood cholesterol increased	2010	Present
Glaucoma	Glaucoma	2010	Present
Acid Reflux	Gastrooesophageal reflux disease	2012	Present
Low Vitamin D	Vitamin D decreased	2015	Present
Arthritis	Arthritis	DEC2017	Present
Muscle Fatigue	Muscle fatigue	2019	Present
Hypotension	Hypotension	AUG2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	17:51
2	Placebo	27AUG2020 (28)	12:59

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Fall	Fall	28AUG2020 (29)	09:30	28AUG2020 (29)	09:30	1
2	INJ&P	Skin laceration	Facial Lacerations	28AUG2020 (29)	09:30	20SEP2020 (52)		24

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FDA-CBER-2021-5683-1788004

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	N	Resolved (28AUG2020)	NOT RELATED/OTHER: Hypotension	2	2	N
2	2	TCN	Y	Resolved (20SEP2020)	NOT RELATED/OTHER: Fall	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	24SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157.48 cm	54.64 kg	22 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
low back pain	Back pain	1987	Present
migraines	Migraine	1987	Present
restless leg syndrome	Restless legs syndrome	1988	Present
total hysterectomy	Hysterectomy	2002	Past
polycystic ovarian disorder	Polycystic ovaries	2002	Past
seizure disorder	Seizure	2003	Present
muscle spasms	Muscle spasms	2008	Present
anxiety	Anxiety	2010	Present
depression	Depression	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteopenia	Osteopenia	2015	Present
seasonal allergies	Seasonal allergy	2015	Present
bipolar disorder	Bipolar disorder	2018	Present
shortness of breath	Dyspnoea	2018	Present
hyperlipidemia	Hyperlipidaemia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	12AUG2020 (1)	14:33
2	BNT162b2	01SEP2020 (21)	13:22

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INV	Blood potassium decreased	Low potassium	03OCT2020 (53)		22OCT2020 (72)		20	2
2	INFEC	Escherichia urinary tract infection	Escherichia coli urinary tract infection	03OCT2020 (53)		22OCT2020 (72)		20	2
3	RENAL	Nephrolithiasis	Kidney Stones	03OCT2020 (53)		22OCT2020 (72)		20	2

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FDA-CBER-2021-5683-1788007

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: HYPOKALEMIA	2	33	Y
2	TC	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: BACTERIAL INFECTION	2	33	Y
3	TC	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: RENAL CALCULUS	2	33	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1936	84	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
187.96 cm	83.91 kg	23.7 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
nearsighted	Myopia	(b) (6) 1936	Present
hypercholesterolemia	Hypercholesterolaemia	1950	Present
drug allergy: penicillin	Drug hypersensitivity	1958	Present
tobacco smoker	Tobacco user	1960	Past
hypertriglyceridemia	Hypertriglyceridaemia	2000	Present
cataracts-bilateral	Cataract	2010	Past
Left hip replacement surgery	Hip arthroplasty	2010	Past
Intraocular Lens Replacement-Bilateral	Intraocular lens implant	2010	Past
left leg weakness	Muscular weakness	2010	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteoarthritis left hip	Osteoarthritis	2010	Present
allergic rhinitis-seasonal	Seasonal allergy	2010	Present
mitral valve replacement	Mitral valve replacement	2012	Past
coronary artery disease	Coronary artery disease	2013	Past
mitral valve disease	Mitral valve disease	2013	Past
basal cell skin cancer	Basal cell carcinoma	2015	Past
vertigo	Vertigo	2015	Present
mild memory loss	Amnesia	2018	Present
atrial fibrillation	Atrial fibrillation	2018	Past
cholecystectomy	Cholecystectomy	2018	Past
Cholelithiasis	Cholelithiasis	2018	Past
clostridium difficile infection	Clostridium difficile infection	2018	Past
hemicolectomy	Colectomy	2018	Past
diverticulosis	Diverticulum	2018	Past
seborrhea-face/scalp	Seborrhoea	2018	Present
vena cava thrombosis	Vena cava thrombosis	2018	Past
deep vein thrombosis	Deep vein thrombosis	JUN2018	Past
ivc filter insertion	Vena cava filter insertion	JUN2018	Past
erectile dysfunction	Erectile dysfunction	2019	Present
abnormal gait	Gait disturbance	14JAN2020	Present
bilateral foot edema	Oedema peripheral	14JAN2020	Past
cough variant asthma	Cough variant asthma	MAY2020	Present
short bowel syndrome	Short-bowel syndrome	18MAY2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10AUG2020 (1)	11:44
2	BNT162b2	31AUG2020 (22)	10:11

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	EYE	Diplopia	double vision	21AUG2020 (12)		22AUG2020 (13)		2	3	N
2	EAR	Vertigo	Worsened Vertigo	21AUG2020 (12)		24AUG2020 (15)		4	3	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (22AUG2020)	NOT RELATED/OTHER: related to vertigo	1	12	Y
2	Y	Resolved (24AUG2020)	NOT RELATED/OTHER: subject history of vertigo exacerbation	1	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	28SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	83.27 kg	27.1 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Strawberry allergy	Food allergy	1953	Present
Penicillin allergy	Drug hypersensitivity	1958	Present
asthma	Asthma	1961	Past
right wrist fracture	Wrist fracture	1965	Past
Kenalog allergy	Drug hypersensitivity	1973	Present
Prednisone allergy	Drug hypersensitivity	1973	Present
Nut allergy	Food allergy	1975	Present
jawbone cyst removal	Bone cyst excision	1979	Past
arthroscopy right knee	Arthroscopy	1985	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arthroscopy left knee	Arthroscopy	1993	Past
hypercholesterolemia	Hypercholesterolaemia	1995	Present
left anterior cruciate ligament reconstruction	Ligament operation	JUL1996	Past
left knee osteoarthritis	Osteoarthritis	1998	Present
iliotibial band friction syndrome	Iliotibial band syndrome	2000	Present
left knee repair	Knee operation	2000	Past
removal of bottom screw left knee	Knee operation	2000	Past
antiphospholipid syndrome	Antiphospholipid syndrome	2002	Present
anxiety	Anxiety	2002	Present
depression	Depression	2002	Present
encephalitis	Encephalitis	2002	Past
right sided hemiplegia	Hemiplegia	2002	Present
hypertension	Hypertension	2002	Present
viral meningitis	Meningitis viral	2002	Past
seasonal allergies	Seasonal allergy	2003	Present
Fatty liver disease	Hepatic steatosis	11FEB2003	Present
spasmodic dysphonia	Spasmodic dysphonia	04AUG2003	Present
sleep apnea	Sleep apnoea syndrome	2004	Present
temporomandibular joint dysfunction	Temporomandibular joint syndrome	26JUL2004	Present
gout	Gout	2005	Present
arthroscopy left knee	Arthroscopy	21NOV2005	Past
right radial styloid tenosynovitis surgical release	Tenotomy	05APR2006	Past
type 2 diabetes	Type 2 diabetes mellitus	2009	Present
left radial styloid tenosynovitis release	Tenotomy	20JUL2009	Past
diabetic neuropathy bilateral feet	Diabetic neuropathy	27OCT2009	Present
diabetic neuropathy bilateral hands	Diabetic neuropathy	27OCT2009	Present

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Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left total knee repair	Knee operation	13MAY2010	Past
right iritis	Iritis	22NOV2010	Past
acute lymes disease	Lyme disease	08AUG2011	Past
partial detached retina left eye	Retinal detachment	12APR2012	Past
revision left total knee replacement	Knee arthroplasty	15AUG2013	Past
revision left total knee replacement	Knee arthroplasty	10OCT2014	Past
laser surgery left eye	Eye laser surgery	19NOV2014	Past
Upper respiratory infection	Upper respiratory tract infection	27JAN2015	Past
iliotibial band release	Fascia release	07JUL2015	Past
left knee pyogenic granuloma removal	Skin neoplasm excision	13NOV2015	Past
right inner thigh fungal infection	Fungal skin infection	28SEP2016	Past
allergy induced edema	Allergic oedema	2017	Present
Norvasc allergy	Drug hypersensitivity	2017	Present
patella femur realignment surgery	Bone operation	14JUN2017	Past
unstable medial collateral ligament left knee	Ligament disorder	26JUL2017	Present
left sided cataracts	Cataract	2018	Past
cataract removal left eye	Cataract operation	2018	Past
Ocular ischemic syndrome	Ocular ischaemic syndrome	2018	Present
Open angle glaucoma	Open angle glaucoma	2018	Present
rosacea	Rosacea	2018	Present
lumbar fusion	Spinal fusion surgery	2018	Past
lumbar laminectomy	Spinal laminectomy	2018	Past
steroid responder	Therapy responder	29OCT2018	Present
lesion removal right elbow	Elbow operation	30JAN2019	Past
Tropical ulcer right elbow	Tropical ulcer	15JUL2019	Past

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Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
revision left total knee replacement	Knee arthroplasty	20AUG2019	Past
injection left iliotibial band	Injection	17APR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	25AUG2020 (1)	11:45
2	Placebo	15SEP2020 (22)	12:02

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Osteomyelitis	osteomyelitis distal phalanx right 3rd toe	31AUG2020 (7)		26SEP2020 (33)		27	3
2	EYE	Retinal detachment	detached left retina	26OCT2020 (63)		28OCT2020 (65)		3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (26SEP2020)	NOT RELATED/OTHER: related to bacterial infection	1	7	Y
2	TC/TCN	N	Resolved (28OCT2020)	NOT RELATED/OTHER: worsening of past medical history	2	42	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
flu vaccine	INFLUENZA VACCINE	09OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	75	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186.2 cm	92 kg	26.5 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
eye glass wearer	Corrective lens user	1949	Present
benign prostatic hyperplasia	Benign prostatic hyperplasia	1990	Past
eczema, bilaterally in arms and legs	Eczema	1990	Present
transurethral resection of prostate	Transurethral prostatectomy	1990	Past
elevated cholesterol, specific level unknown	Blood cholesterol increased	2010	Present
diabetes type II without any history of ketoacidosis	Type 2 diabetes mellitus	2010	Present
diabetic neuropathy of feet, bilaterally	Diabetic neuropathy	2011	Present
insomnia	Insomnia	2011	Present
atrial fibrillation	Atrial fibrillation	2012	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
coronary artery disease	Coronary artery disease	2012	Present
high blood pressure	Hypertension	2012	Present
full denture wearer	Denture wearer	2015	Present
edema in ankles	Oedema peripheral	2016	Present
edema in both legs	Oedema peripheral	2016	Present
osteoporosis	Osteoporosis	2016	Present
bilateral cataracts	Cataract	2018	Past
heart failure with reserved ejection fraction	Cardiac failure	2019	Present
decreased hearing in both ears	Hypoacusis	2019	Present
chronic obstructive pulmonary disease, severe	Chronic obstructive pulmonary disease	JAN2019	Present
peripheral neuropathy of feet, bilaterally	Neuropathy peripheral	APR2019	Present
urinary incontinence, urge	Urge incontinence	AUG2019	Present
chronic kidney disease, stage 3	Chronic kidney disease	OCT2019	Present
dizziness	Dizziness	JAN2020	Past
cataract surgery in both eyes	Cataract operation	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	13:32

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Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Asthenia	generalized weakness, intermittent	SEP2020 ()		ONGOING			2
2	CARD	Atrial fibrillation	Atrial fibrillation with rapid ventricular response	08OCT2020 (31)		13OCT2020 (36)		6	2
3	INJ&P	Fall	Frequent falls	SEP2020 ()		ONGOING			2
4	METAB	Hypovolaemia	hypovolemia	08OCT2020 (31)		13OCT2020 (36)		6	2
5	METAB	Hypovolaemia	hypovolemia	18OCT2020 (41)		25OCT2020 (48)		8	2
6	VASC	Orthostatic hypotension	Hypotension, orthostatic	18OCT2020 (41)		25OCT2020 (48)		8	3
7	NERV	Paraesthesia	tingling of bilateral limbs, intermittent	SEP2020 ()		ONGOING			1
8	INJ&P	Skin abrasion	abrasion of right forearm	SEP2020 ()		ONGOING			1
9	NERV	Syncope	Syncope	08OCT2020 (31)		13OCT2020 (36)		6	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT			N
2	TC	N	Resolved (13OCT2020)	NOT RELATED/OTHER: Hypovolemia	1	31	N
3	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT			N
4	TC	N	Resolved (13OCT2020)	NOT RELATED/OTHER: due to poor intake	1	31	N
5	N	N	Resolved (25OCT2020)	NOT RELATED/OTHER: Inadequate intake	1	41	N
6	TC	Y	Resolved (25OCT2020)	NOT RELATED/OTHER: Hypovolemia due to poor oral intake	1	41	Y
7	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT			N
8	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT			N
9	TC	Y	Resolved (13OCT2020)	NOT RELATED/OTHER: Hypovolemia	1	31	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	Asian	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	50 kg	19.5 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
eye glass wearer	Corrective lens user	1979	Present
myopia	Myopia	1979	Present
postmenopausal state	Postmenopause	2016	Present
recurrent heartburn	Dyspepsia	2019	Present
palpitations	Palpitations	JUL2020	Present
cervical spine degeneration	Spinal osteoarthritis	JUL2020	Present
vitamin D deficiency	Vitamin D deficiency	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	13:35
2	BNT162b2	16OCT2020 (22)	15:23

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CONG	Heart disease congenital	congenital heart anomaly	02NOV2020 (39)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC	Y	Yes	NOT RELATED/OTHER: Congenital heart anomaly	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	62	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	112 kg	35 kg/m2	30JUL2020 (-1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ETOH abuse	Alcohol abuse	2000	Past
Coronary Artery Disease	Coronary artery disease	2008	Present
Hyperlipidemia	Hyperlipidaemia	2008	Present
Hypertension	Hypertension	2008	Present
Open Heart Surgery	Cardiac operation	2009	Past
Benign Prostate Hyperplasia	Benign prostatic hyperplasia	2012	Present
Congestive Hearth Failure (CHF)	Cardiac failure congestive	2012	Present
Strock (CVA)	Cerebrovascular accident	2014	Past
Ischemic colitis	Colitis ischaemic	2017	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Colectomy Hartman	Colostomy	2017	Past
Bipolar Disorder	Bipolar disorder	2018	Present
Schizophrenia with paranoia	Schizophrenia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31JUL2020 (1)	10:08
2	Placebo	21AUG2020 (22)	11:11

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	Bipolar disorder	Worsening Bipolar Disorder	24AUG2020 (25)	08:00	04SEP2020 (36)	14:00	12	3
2	NERV	Syncope	Syncope	05OCT2020 (67)	10:00	05OCT2020 (67)	10:00	1	3
3	INFEC	Urinary tract infection	Urinary tract infection	05OCT2020 (67)	10:00	14OCT2020 (76)	10:00	10	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (04SEP2020)	NOT RELATED/OTHER: Psychiatric illness	2	4	Y

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Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	TC	N	Resolved (05OCT2020)	NOT RELATED/OTHER: Urinary tract Infection	2	46	N
3	N	Y	Resolved (14OCT2020)	NOT RELATED/OTHER: Escherichia coli	2	46	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30JUL2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1938	81	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	97.55 kg	29.9 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic Lower Back Pain	Back pain	1972	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2008	Present
Elevated Cholesterol	Blood cholesterol increased	2008	Present
Hypertension	Hypertension	2008	Present
Osteoarthritis (Both Knees and Hands)	Osteoarthritis	2016	Present
Perennial Allergic Rhinitis	Rhinitis perennial	2017	Present
Right Partial Knee replacement	Knee arthroplasty	MAY2017	Past
Prostatitis	Prostatitis	11APR2019	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	17:00
2	Placebo	01SEP2020 (21)	10:18

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Intestinal obstruction	Intestinal Obstruction	20AUG2020 (9)		03SEP2020 (23)		15

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (03SEP2020)	NOT RELATED/OTHER: Unknown	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	29SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	54.09 kg	23.2 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	1949	Past
appendicitis	Appendicitis	1949	Past
tonsillectomy	Tonsillectomy	1953	Past
tonsillitis	Tonsillitis	1953	Past
rheumatoid arthritis	Rheumatoid arthritis	1970	Present
left fractured femur repair	Fracture treatment	01DEC1971	Past
bunions to left foot	Foot deformity	1979	Past
right hammer toe	Foot deformity	1979	Past
hammer toe repair to right foot	Toe operation	1979	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
left hand carpal tunnel syndrome	Carpal tunnel syndrome	1983	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	1990	Present
post menopausal	Postmenopause	1994	Present
anxiety	Anxiety	2009	Present
bilateral cataracts	Cataract	2015	Present
left fractured femur	Femur fracture	01DEC2017	Past
gout	Gout	MAR2018	Present
left inner ear infection	Labyrinthitis	12SEP2018	Past
ER visit for kidney stones	Nephrolithiasis	AUG2020	Past
kidney stones	Nephrolithiasis	AUG2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	10:06
2	BNT162b2	24SEP2020 (22)	09:37

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Adrenal gland cancer	ADRENAL ADENOCARCINOMA	20OCT2020 (48)		ONGOING	

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Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		4	TC	Y	Yes	NOT RELATED/OTHER: IDIOPATHIC	2	27	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	10NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	83.3 kg	29.9 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
keloid scar (left knee)	Keloid scar	1966	Present
depression	Depression	1995	Present
cataplexy	Cataplexy	2000	Present
narcolepsy	Narcolepsy	2000	Present
low testosterone	Blood testosterone decreased	2010	Present
erectile dysfunction	Erectile dysfunction	2010	Present
left shoulder injury	Limb injury	2011	Past
left shoulder replacement	Shoulder arthroplasty	2011	Past
pre-diabetic	Glucose tolerance impaired	2013	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	2015	Present
circadian rhythm sleep disorder	Circadian rhythm sleep disorder	2018	Present
reading glasses	Corrective lens user	2018	Present
sleep apnea	Sleep apnoea syndrome	2018	Present
overweight/obese	Obesity	2019	Present
hyperlipidemia	Hyperlipidaemia	FEB2020	Present
pulmonary nodule	Pulmonary mass	APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	14:57
2	Placebo	09SEP2020 (24)	13:19

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholecystitis acute	acute cholecystitis	14OCT2020 (59)		17OCT2020 (62)		4
2	INFEC	Urinary tract infection	urinary tract infection	15OCT2020 (60)		17OCT2020 (62)		3

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Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN	Y	Resolved (17OCT2020)	NOT RELATED/OTHER: gallstones	2	36	Y
2	1	TC	N	Resolved (17OCT2020)	NOT RELATED/OTHER: bacterial infection	2	37	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
fluzone quadrivalent	INFLUENZA VACCINE INACT SPLIT 4V	10OCT2020
shingrix	VARICELLA ZOSTER VACCINE RGE (CHO)	06NOV2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1956	64	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline
No Vital Signs - Baseline

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1974	Present
Hypertension	Hypertension	1979	Present
Hyperlipidemia	Hyperlipidaemia	2000	Present
Osteopenia	Osteopenia	2010	Present
Spontaneous Coronary artery dissection	Coronary artery dissection	07DEC2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29JUL2020 (1)	14:44
2	BNT162b2	17AUG2020 (20)	09:51

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1			Myocardial Ischemia- Related to spontaneous coronary artery dissection	28AUG2020 (31)		28AUG2020 (31)		1	1	N	N
2	CARD	Coronary artery dissection	Spontaneous coronary artery dissection	28AUG2020 (31)		28AUG2020 (31)		1	4	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (28AUG2020)	NOT RELATED/OTHER: Suffered some myocardial ischemia at the time of dissection	2	12	N
2	Resolved (28AUG2020)	NOT RELATED/OTHER: History of coronary artery dissection	2	12	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	29JUL2020	
Withdrawn	VACCINATION	28AUG2020	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	17SEP2020	WITHDRAWAL BY SUBJECT

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	40	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
183.79 cm	102.09 kg	30.2 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	01NOV1985	Present
Allergy to cats	Allergy to animal	01AUG1988	Present
Allergy to bees	Allergy to arthropod sting	01AUG1988	Present
allergy to penicillin	Drug hypersensitivity	01AUG1988	Present
Allergy to shrimp	Food allergy	01AUG1988	Present
Gout	Gout	01SEP2013	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31JUL2020 (1)	09:28
2	BNT162b2	20AUG2020 (21)	14:57

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	IMMUN	Anaphylactic reaction	Anaphylaxis Status Post Bee Sting	28AUG2020 (29)	14:00	28AUG2020 (29)	20:00	1	4	TC
2	INFEC	Infected bite	Cellulitis Status Post Bee Sting	30AUG2020 (31)	08:00	09SEP2020 (41)	08:00	11	2	TC
3	GENRL	Injection site pain	Injection Site Pain	31JUL2020 (1)	12:00	01AUG2020 (2)	08:00	2	1	N
4	GENRL	Injection site swelling	Injection Site Swelling	31JUL2020 (1)	12:00	01AUG2020 (2)	08:00	2	2	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (28AUG2020)	NOT RELATED/OTHER: Subject with history of allergy to bee venom	2	9	Y
2	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Subject with history of allergy to bee venom	2	11	N
3	N	Resolved (01AUG2020)	Study Treatment	1	1	N
4	N	Resolved (01AUG2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	17SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.8 cm	104.45 kg	34.9 kg/m2	07AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
appendectomy	Appendicectomy	01OCT1965	Past
lung cancer	Lung neoplasm malignant	01OCT2011	Past
cardiac catheterization	Catheterisation cardiac	07DEC2011	Present
hyperlipidemia	Hyperlipidaemia	07DEC2011	Present
R upper lung lobectomy	Lung lobectomy	11JAN2012	Past
diminished lung function due to lung surgery	Pulmonary function test decreased	01FEB2012	Present
Gallbladder Attacks	Gallbladder disorder	2013	Present
hypertension	Hypertension	01APR2018	Present
pre-diabetes	Glucose tolerance impaired	01APR2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07AUG2020 (1)	12:20
2	Placebo	28AUG2020 (22)	10:20

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	HEPAT	Cholecystitis acute	Acute Cholecystitis	16SEP2020 (41)	08:00	30SEP2020 (55)		15	4	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (30SEP2020)	NOT RELATED/OTHER: Subject with history of gallstones and associated gallbladder wall thickening	2	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07AUG2020	
Completed	VACCINATION	25SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.66 cm	69.27 kg	26.8 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
intravenous pyelogram dye allergy	Contrast media allergy	1956	Present
hypertension	Hypertension	01SEP1995	Present
post-menopausal (19yrs)	Postmenopause	2001	Present
hyperlipidemia	Hyperlipidaemia	01SEP2005	Present
GI Cramping	Gastrointestinal pain	2012	Present
Cholecystectomy	Cholecystectomy	01SEP2012	Past
breast cancer bilateral	Breast cancer	24JUN2015	Past
breast lumpectomy	Breast conserving surgery	01AUG2015	Past
Macular degeneration	Macular degeneration	01DEC2018	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	13:45
2	BNT162b2	25SEP2020 (24)	10:37

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GASTR	Gastrointestinal pain	Worsening GI Cramping	08SEP2020 (7)	08:00	20SEP2020 (19)		13	3	N	N
2	GASTR	Small intestinal obstruction	Small Bowel Obstruction	08SEP2020 (7)		20SEP2020 (19)		13	3	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (20SEP2020)	NOT RELATED/OTHER: Subject has history of intermittent GI issues	1	7	N
2	Resolved (20SEP2020)	NOT RELATED/OTHER: Pre-existing condition (GI cramping). See Med Hx	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	23OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1950	70	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	73.64 kg	23.9 kg/m2	03AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Cerebral vascular accident	Cerebrovascular accident	25AUG2017	Past
Paroxysmal atrial fibrillation	Atrial fibrillation	19JAN2018	Present
Hiatal hernia	Hiatus hernia	09APR2018	Present
Hypertension	Hypertension	09APR2018	Present
Hypercholesterolemia	Hypercholesterolaemia	12JUL2018	Present
Migraines	Migraine	12JUL2018	Present
Benign prostatic hyperplasia	Benign prostatic hyperplasia	20MAY2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	03AUG2020 (1)	13:58
2	Placebo	28AUG2020 (26)	11:48

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	VASC	Orthostatic hypotension	Possible postural hypotension	31AUG2020 (29)	14:00	31AUG2020 (29)	16:00	1	4	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (31AUG2020)	NOT RELATED/OTHER: Neurology noted indicated likely postural hypoperfusion	2	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03AUG2020	
Completed	VACCINATION	25SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	70.59 kg	22.9 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy to penicillin	Drug hypersensitivity	1947	Present
Hysterectomy	Hysterectomy	1973	Past
Hypertension	Hypertension	12JUL2007	Present
Atrial fibrillation	Atrial fibrillation	11APR2015	Present
Recurrent Blepharitis	Blepharitis	23AUG2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05AUG2020 (1)	10:22
2	BNT162b2	29AUG2020 (25)	09:46

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Colitis	Colitis	05SEP2020 (32)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: Recent antibiotic use	2	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
Completed	VACCINATION	28SEP2020	
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	82 kg	28.3 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Major Depressive Disorder	Major depression	2018	Present
Schizophrenia	Schizophrenia	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	13:41
2	Placebo	04SEP2020 (24)	15:20

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Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Craniocerebral injury	Closed head injury	19AUG2020 (8)		19AUG2020 (8)		1	3
2	PSYCH	Suicidal ideation	Suicidal Ideation	19AUG2020 (8)		21AUG2020 (10)		3	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (19AUG2020)	NOT RELATED/OTHER: Subject was in "an altercation"	1	8	N
2	TC	Y	Resolved (21AUG2020)	NOT RELATED/OTHER: History of Major Depressive Disorder	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Withdrawn	VACCINATION	04NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
176.53 cm	68.18 kg	21.8 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Poison ivy allergy	Dermatitis contact	1973	Present
Bactrim allergy	Drug hypersensitivity	1985	Present
Depression, well-controlled	Depression	2010	Present
Right hip replacement	Hip arthroplasty	2015	Past
palpitation	Palpitations	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	12:32
2	Placebo	17SEP2020 (21)	10:35

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Pericardial effusion	small pericardial effusion	08OCT2020 (42)		ONGOING			2	N	N
2	CARD	Tachycardia	tachycardia	07OCT2020 (41)	10:00	08OCT2020 (42)	12:00	2	3	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: the volunteer has been having the tachycardia events in the past	2	22	N
2	Resolved (08OCT2020)	NOT RELATED/OTHER: patient has history of palpitation for the past 4 months	2	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	34	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	66.36 kg	22.2 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Wisdom teeth removal	Wisdom teeth removal	2003	Past
Depression, controlled	Depression	2016	Present
Hypothyroidism, controlled	Hypothyroidism	2017	Present
Seasonal allergies	Seasonal allergy	2017	Present
c-section delivery	Delivery	10JAN2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	14:52

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Dizziness	dizziness	24SEP2020 (25)		25SEP2020 (26)		2	2
2	MUSC	Intervertebral disc protrusion	disc herniation	14SEP2020 (15)		ONGOING			2
3	NERV	Paraesthesia	Paresthesias of Skin	21SEP2020 (22)		28SEP2020 (29)		8	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (25SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	25	N
2	TC	N	Yes	NOT RELATED/OTHER: Disc Herniation at L5-S1	1	15	N
3	TC	Y	Resolved (28SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	66	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	99.55 kg	30.5 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Clot Right Leg	Thrombosis	1972	Past
Pulmonary Embolism	Pulmonary embolism	1978	Past
High Cholesterol	Blood cholesterol increased	2016	Present
DVT	Deep vein thrombosis	15DEC2018	Past
benign tumor of thymus	Benign neoplasm of thymus	JUL2019	Past
Thymectomy	Thymectomy	JUL2019	Past
cyst of the thymus gland	Thymic cyst	JUL2019	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	09:26
2	BNT162b2	21SEP2020 (22)	13:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Atelectasis	Bibasilar Atelectasis on chest xray	10SEP2020 (11)		10OCT2020 (41)		31	1
2	RESP	Interstitial lung disease	Interstitial Pneumonitis	09SEP2020 (10)		09SEP2020 (10)		1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (10OCT2020)	NOT RELATED/OTHER: low inspiratory effort	1	11	N
2	N	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: ideopathic origin	1	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	26OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	51	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	87.73 kg	28.5 kg/m2	03SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasovagal Syncope	Syncope	2000	Present
High Cholesterol	Blood cholesterol increased	2003	Present
Depression	Depression	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	03SEP2020 (1)	09:45
2	BNT162b2	25SEP2020 (23)	11:10

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrioventricular block first degree	1 Degree AV block	27SEP2020 (25)		27SEP2020 (25)		1	2
2	CARD	Bradycardia	Acute Bradycardia	27SEP2020 (25)		28SEP2020 (26)		2	3
3	NERV	Loss of consciousness	Loss of consciousness	27SEP2020 (25)	10:00	29SEP2020 (27)	16:00	3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (27SEP2020)	NOT RELATED/OTHER: Idiopathic origin	2	3	N
2	TC	Y	Resolved (28SEP2020)	NOT RELATED/OTHER: Vasovagal response	2	3	Y
3	N	Y	Resolved (29SEP2020)	NOT RELATED/OTHER: History of vasovagal syncope	2	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	03SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	58	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	102.91 kg	33.9 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Post traumatic stress disorder	Post-traumatic stress disorder	2014	Present
Total left hip replacement	Hip arthroplasty	2015	Past
Hypertension	Hypertension	2016	Present
insomnia	Insomnia	2016	Present
Osteoarthritis	Osteoarthritis	2016	Present
Chronic pain syndrome	Pain	2016	Present
Surgical repair of the right bicep	Muscle operation	2017	Past
Tear of the right bicep	Muscle rupture	2017	Past
Depressive disorder	Depression	02SEP2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	13:21
2	BNT162b2	14OCT2020 (20)	12:37

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Pulmonary embolism	Pulmonary Emboli	08NOV2020 (45)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Yes	NOT RELATED/OTHER: unknown-pending full report	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	57.73 kg	21.8 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	14SEP2012	Present
seasonal allergies	Seasonal allergy	03DEC2012	Present
Anxiety	Anxiety	13SEP2018	Present
menopause	Menopause	2019	Present
mennorrhagia	Menorrhagia	18APR2019	Present
IRREGULAR MENSTRUAL CYCLE	Menstruation irregular	18APR2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	12:46
2	Placebo	30SEP2020 (21)	11:57

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Abdominal pain lower	Left Lower Quadrant Pain	25SEP2020 (16)		ONGOING		
2	INV	Blood chloride decreased	Decreased Chloride (94)	24SEP2020 (15)		ONGOING		
3	INV	Blood sodium decreased	Decreased Sodium (131)	24SEP2020 (15)		ONGOING		
4	INV	High density lipoprotein increased	Increased HDL (95)	18SEP2020 (9)		ONGOING		
5	REPRO	Ovarian mass	Ovarian Mass	21SEP2020 (12)		ONGOING		
6	INV	Urine ketone body present	Trace Ketones (Urinalysis)	24SEP2020 (15)		ONGOING		
7	INV	White blood cells urine positive	Trace Leukocytes in Urinalysis	24SEP2020 (15)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TCN	N	Yes	NOT RELATED/OTHER: Not related to the study treatment	1	16	N
2	1	N	N	Yes	NOT RELATED/OTHER: Not related to study treatment	1	15	N
3	1	N	N	Yes	NOT RELATED/OTHER: Not related to the study	1	15	N
4	1	N	N	Yes	NOT RELATED/OTHER: Not related to the study treatment	1	9	N

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	2	TCN	Y	Yes	NOT RELATED/OTHER: Ovarian mass of unknown origin	1	12	Y
6	1	N	N	Yes	NOT RELATED/OTHER: Not related to study treatment	1	15	N
7	1	N	N	Yes	NOT RELATED/OTHER: Not related to the study treatment	1	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152 cm	72.8 kg	31.5 kg/m2	24SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
intermittent heart murmur	Cardiac murmur	1954	Present
gabapentin allergy	Drug hypersensitivity	2012	Present
lyrica allergy	Drug hypersensitivity	2012	Present
hernia	Hernia	2013	Present
lumbar degenerative disc disease	Intervertebral disc degeneration	2013	Present
partial denture - WEARER	Denture wearer	2016	Present
left thumb osteoarthritis	Osteoarthritis	2018	Present
right knee osteoarthritis	Osteoarthritis	2018	Present
type 2 diabetes	Type 2 diabetes mellitus	2019	Present

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Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
femoral hernia	Femoral hernia	JAN2020	Present
hyperlipidemia	Hyperlipidaemia	JAN2020	Present
hypertension	Hypertension	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24SEP2020 (1)	13:20
2	Placebo	15OCT2020 (22)	12:31

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	RESP	Cough	severe cough	01NOV2020 (39)	08:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: medical	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	88.09 kg	28.6 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic Pancreatitis	Pancreatitis chronic	2014	Present
Sinusitus	Sinusitis	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	14:07
2	BNT162b2	09SEP2020 (24)	09:08

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Myalgia	General Muscle Pain	17AUG2020 (1)	18:00	19AUG2020 (3)		3
2	GASTR	Pancreatitis	Worsening Pancreatitis	21AUG2020 (5)		23SEP2020 (38)		34

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (19AUG2020)	Study Treatment	1	1	N
2	3	N	Y	Resolved (23SEP2020)	NOT RELATED/OTHER: Pancreatitis	1	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.99 cm	82.45 kg	27.2 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arthroscopic surgery left knee	Knee operation	1970	Past
osteoarthritis	Osteoarthritis	1971	Present
anxiety	Anxiety	1972	Present
Bipolar depression	Bipolar disorder	1972	Present
nervous breakdoen	Mental disorder	1972	Past
allergy to codeine	Drug hypersensitivity	1983	Present
allergy to thorazine	Drug hypersensitivity	1983	Present
arthroscopic surgery left knee	Knee operation	1985	Past
dyspepsia	Dyspepsia	1989	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroid	Hypothyroidism	1990	Present
hyoid bone removed	Ostectomy	1990	Past
arthroscopic surgery left knee	Knee operation	1991	Past
seborrheic dermatitis	Seborrhoeic dermatitis	1995	Present
Type II diabetes	Type 2 diabetes mellitus	1995	Past
colitis	Colitis	2000	Past
irritable bowel	Irritable bowel syndrome	2000	Present
hypertension	Hypertension	2008	Present
insomnia	Insomnia	2010	Present
cervical disc disease	Intervertebral disc disorder	2010	Past
cervical disc surgery	Intervertebral disc operation	2010	Past
gastric bypass	Gastric bypass	2012	Past
thoracic spine disc disease	Intervertebral disc disorder	2013	Past
surgery T-3 disc	Intervertebral disc operation	2013	Past
anemia	Anaemia	2014	Past
arthroscopic surgery right knee	Knee operation	2015	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	19AUG2020 (1)	12:42
2	Placebo	10SEP2020 (23)	10:51

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Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	Bipolar disorder	worsening of bipolar disorder	29OCT2020 (72)		06NOV2020 (80)		9	3
2	RESP	Cough	cough	03NOV2020 (77)		06NOV2020 (80)		4	1
3	RENAL	Pollakiuria	urinary frequency	06OCT2020 (49)		01NOV2020 (75)		27	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (06NOV2020)	NOT RELATED/OTHER: historical condition with variability	2	50	Y
2	N	N	Resolved (06NOV2020)	NOT RELATED/OTHER: unknown	2	55	N
3	N	N	Resolved (01NOV2020)	NOT RELATED/OTHER: unknown	2	27	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	08OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	174.55 kg	56.7 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	DEC1952	Present
tonsillectomy	Tonsillectomy	1961	Past
morbid obesity	Obesity	1980	Present
hiatal hernia repair	Hernia hiatus repair	1988	Past
hiatal hernia	Hiatus hernia	1988	Past
hypertension	Hypertension	1997	Present
hypercholesterolemia	Hypercholesterolaemia	2006	Present
failed prostatectomy	Procedural failure	2007	Past
prostate cancer	Prostate cancer	2007	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
prostatism	Prostatism	2007	Present
low back pain	Back pain	2010	Present
diabetic neuropathy	Diabetic neuropathy	2018	Present
Type II diabetes	Type 2 diabetes mellitus	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	09:59
2	Placebo	21SEP2020 (22)	08:11

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Malignant melanoma	melanoma left shoulder	04SEP2020 (5)		08OCT2020 (39)		35

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (08OCT2020)	NOT RELATED/OTHER: unknown	1	5	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.59 cm	60.59 kg	21.5 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Brazil Nut Allergy	Food allergy	1964	Present
Penicillin Allergy	Drug hypersensitivity	1965	Present
Dislocated Left Shoulder	Joint dislocation	1978	Past
Left Shoulder Surgery	Shoulder operation	25DEC1979	Past
Dislocated Right Shoulder	Joint dislocation	1996	Past
Right Shoulder Surgery	Shoulder operation	OCT2000	Past
Right Hip Osteoarthritis	Osteoarthritis	2008	Past
Right Hip Surgery	Hip surgery	AUG2016	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Correct Failed Right Shoulder Surgery	Shoulder operation	2017	Past
Right Shoulder Surgery	Shoulder operation	OCT2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	16:58
2	BNT162b2	08SEP2020 (21)	14:57

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	MUSC	Arthropathy	WIDENINNG OFACROMIOCLAVICULAR JOINT SPACE (GRADE 1)	06OCT2020 (49)		ONGOING			2	TC	N
2	INJ&P	Facial bones fracture	FRACTURE OF ROOF OF RIGHT ORBITAL (GRADE 3)	06OCT2020 (49)		ONGOING			3	TC	Y
3	INJ&P	Fall	FALL FROM BICYCLE	06OCT2020 (49)	08:20	06OCT2020 (49)	08:20	1	2	N	N
4	INJ&P	Muscle strain	PARTIAL TEAR OF THE RIGHT TRAPEZIUS MUSCLE (GRADE 1)	06OCT2020 (49)		ONGOING			2	TC	N

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Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
5	RESP	Oropharyngeal pain	SORE THROAT	23AUG2020 (5)		30AUG2020 (12)		8	1	N	N
6	NERV	Subarachnoid haemorrhage	SUBARACHNOID HEMORRHAGE	06OCT2020 (49)	08:20	17OCT2020 (60)		12	4	TC	Y
7	INJ&P	Traumatic intracranial haemorrhage	TRAUMATIC INTRACRANIAL HEMORRHAGE	06OCT2020 (49)		ONGOING			3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: BICYCLE ACCIDENT	2	29	N
2	Yes	NOT RELATED/OTHER: BICYCLE ACCIDENT	2	29	Y
3	Resolved (06OCT2020)	NOT RELATED/OTHER: NO UNDERLYING CAUSE	2	29	N
4	Yes	NOT RELATED/OTHER: BICYCLE ACCIDENT	2	29	N
5	Resolved (30AUG2020)	NOT RELATED/OTHER: UNRELATED NEW MEDICAL CONDITION	1	5	N
6	Resolved (17OCT2020)	NOT RELATED/OTHER: FALL FROM BICYCLE	2	29	Y
7	Yes	NOT RELATED/OTHER: BICYCLE ACCIDENT	2	29	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
TETANUS-DIPHTHERIA VACCINE	DIPHTHERIA VACCINE;TETANUS VACCINE	06OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.2 cm	74 kg	26.5 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 1 Diabetes	Type 1 diabetes mellitus	AUG2014	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	11:44

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	VASC	Deep vein thrombosis	DEEP VEIN THROMBOSIS	31AUG2020 (12)		09SEP2020 (21)		10	3	TC
2	MUSC	Musculoskeletal stiffness	right shoulder stiffness	05SEP2020 (17)		07SEP2020 (19)		3	1	TCN
3	RESP	Pulmonary embolism	PULMONARY EMBOLISM	31AUG2020 (12)		02SEP2020 (14)		3	3	TC

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: MEDICAL HISTORY - TYPE 1 DIABETES	1	12	Y
2	N	Resolved (07SEP2020)	NOT RELATED/OTHER: unknown new medical condition	1	17	N
3	N	Resolved (02SEP2020)	NOT RELATED/OTHER: DEEP VEIN THROMBOSIS	1	12	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Withdrawn	VACCINATION	08SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1998	22	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.3 cm	83.6 kg	32.5 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
C-section	Caesarean section	16MAY2019	Past
Obesity	Obesity	06JUN2019	Present
Menorrhagia	Menorrhagia	03JAN2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	15:26
2	Placebo	10SEP2020 (22)	16:04

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PREG	Abortion spontaneous incomplete	INCOMPLETE SPONTANEOUS ABORTION	04OCT2020 (46)		07OCT2020 (49)		4	3
2	RESP	Haemoptysis	HEMOPTYSIS	04OCT2020 (46)		04OCT2020 (46)		1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	Y	Resolved (07OCT2020)	NOT RELATED/OTHER: UNKNOWN ETIOLOGY	2	25	Y
2	N	N	Resolved (04OCT2020)	NOT RELATED/OTHER: UNKNOWN ETIOLOGY	2	25	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	12OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1951	69	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.47 cm	64.09 kg	23.6 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis Multiple Joints	Osteoarthritis	2004	Present
Post Menopause	Postmenopause	2010	Present
Depression	Depression	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02SEP2020 (1)	09:34
2	BNT162b2	24SEP2020 (23)	09:11

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Transient ischaemic attack	Suspected Transient Ischemic Attack	27OCT2020 (56)	05:30	28OCT2020 (57)	14:00	2	3
2	NERV	Tremor	Tremor	13OCT2020 (42)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (28OCT2020)	NOT RELATED/OTHER: Atherosclerotic vs Embolic disease	2	34	Y
2	N	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	05NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1935	85	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	90.3 kg	27.9 kg/m2	05AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
osteoarthritis	Osteoarthritis	2010	Present
type II diabetes	Type 2 diabetes mellitus	2010	Present
chronic constipation	Constipation	2012	Present
hypertension	Hypertension	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	05AUG2020 (1)	12:34
2	Placebo	04NOV2020 (92)	10:57

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INFEC	Pneumonia	pneumonia	11NOV2020 (99)		ONGOING	
2	INV	SARS-CoV-2 test positive	SARS-COV-2 Positive	10NOV2020 (98)	03:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: viral syndrome	2	8	Y
2		3	N	Y	Yes	NOT RELATED/OTHER: viral syndrome	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	05AUG2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	61	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	69 kg	23.6 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetes Type II	Type 2 diabetes mellitus	1999	Present
Hyperlipidemia	Hyperlipidaemia	2000	Present
Hypertension	Hypertension	2000	Present
Nearsighted	Myopia	2010	Present
smoking	Tobacco user	10AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10AUG2020 (1)	11:20
2	Placebo	02SEP2020 (24)	11:57

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Pneumonia	pneumonia	03SEP2020 (25)		13SEP2020 (35)		11	3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (13SEP2020)	NOT RELATED/OTHER: unblinded per tx physician physician request sponsor notify of unblinded	2	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	01OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1981	39	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	118.64 kg	37.4 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2000	Present
Anxiety	Anxiety	2010	Present
Hypothyroidism	Hypothyroidism	APR2011	Present
Allergic Rhinitis	Rhinitis allergic	07JUN2016	Present
S/p laparoscopic sleeve gastrectomy	Gastrectomy	10MAY2018	Past
Low Back Pain	Back pain	09JUL2018	Present
Panic Attacks	Panic attack	24JUL2019	Present
Hysterectomy	Hysterectomy	31JAN2020	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	15:51
2	Placebo	09SEP2020 (24)	11:53

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	HEPAT	Cholecystitis acute	Acute Cholecystitis	21AUG2020 (5)		22AUG2020 (6)		2	3	TC/TCN	Y
2	HEPAT	Cholelithiasis	Cholelithiasis	21AUG2020 (5)		22AUG2020 (6)		2	2	TCN	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (22AUG2020)	NOT RELATED/OTHER: Cholelithiasis and sudden weight loss due to baratric surgery 2018	1	5	Y
2	Resolved (22AUG2020)	NOT RELATED/OTHER: Sudden weight loss due to bariatric surgery	1	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Fluzone (Influenza vaccine)	INFLUENZA VACCINE	06OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
190.5 cm	135.45 kg	37.2 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Iron Deficiency anemia	Iron deficiency anaemia	26AUG1998	Present
Lumbar Radiculopathy	Lumbar radiculopathy	2010	Present
Acid Reflux disease	Gastrooesophageal reflux disease	08AUG2012	Present
Paroxysmal Atrial Fibrillation	Atrial fibrillation	24OCT2012	Present
Coronary arteriosclerosis	Arteriosclerosis coronary artery	13AUG2014	Present
Hematochezia	Haematochezia	08OCT2015	Past
Chronic Gout	Gout	30AUG2016	Present
Peripheral Neuropathy	Neuropathy peripheral	30AUG2016	Present
Type 2 Diabetes	Type 2 diabetes mellitus	09MAR2017	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	28AUG2017	Present
Macular degeneration	Macular degeneration	2018	Present
Benign Hyperplasia Prostate	Benign prostatic hyperplasia	10OCT2018	Present
Hyperlipidemia	Hyperlipidaemia	10OCT2018	Present
Hypothyroidism	Hypothyroidism	10OCT2018	Present
Mild Dementia	Dementia	28JAN2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	09:24
2	Placebo	17SEP2020 (21)	08:30

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Angina unstable	Unstable Angina Pectoris	20OCT2020 (54)		20OCT2020 (54)		1	2

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Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (20OCT2020)	NOT RELATED/OTHER: known Coronary artery disease	2	34	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	55	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	88.64 kg	28 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	1987	Present
smoker	Tobacco user	1990	Present
hyperlipidemia	Hyperlipidaemia	1998	Present
type 2 diabetes	Type 2 diabetes mellitus	1998	Present
type 2 diabetes neuropathy	Diabetic neuropathy	2014	Present
cervicalgia	Neck pain	18SEP2014	Present
attention deficit disorder	Attention deficit hyperactivity disorder	10MAR2017	Present
hypogonadism, testicular	Hypogonadism male	15NOV2019	Present
polycythemia	Polycythaemia	14MAY2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	15:48
2	BNT162b2	29SEP2020 (20)	15:30

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	NERV	Cerebrovascular accident	Cerebrovascular accident	21OCT2020 (42)		ONGOING			3	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Yes	NOT RELATED/OTHER: underlying risk factors, smoker, Diabetes, polycythemia	2	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.88 cm	164.2 kg	49.1 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal Allergies	Seasonal allergy	1963	Present
Hypertension	Hypertension	1980	Present
Chronic Deep Vein Thrombosis (DVT)	Deep vein thrombosis	1998	Present
Type II Diabetes	Type 2 diabetes mellitus	1998	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	11:05
2	Placebo	29SEP2020 (22)	10:06

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Cellulitis	Cellulitis of left lower leg	01OCT2020 (24)		ONGOING			3	TC/TCN	Y
2	INJ&P	Limb injury	Wound of left lower leg	12SEP2020 (5)		30SEP2020 (23)		19	3	TC	N
3	BLOOD	Neutropenia	Neutropenia	01OCT2020 (24)		ONGOING			3	TC/TCN	Y
4	BLOOD	Thrombocytopenia	Thrombocytopenia	01OCT2020 (24)		ONGOING			2	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: underline comorbidities pt with a hx of Type II Diabetes and morbid obesity	2	3	Y
2	Resolved (30SEP2020)	NOT RELATED/OTHER: injury to leg.	1	5	N
3	Yes	NOT RELATED/OTHER: underline comorbidities pt with a hx of Type II Diabetes and morbid obesity	2	3	Y
4	Yes	NOT RELATED/OTHER: Cellulitis	2	3	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline
No Vital Signs - Baseline

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Microdiscectomy Lumbar spine	Intervertebral disc operation	1980	Past
hypercholesterolaemia	Hypercholesterolaemia	2005	Present
hypertension	Hypertension	2005	Present
hypothyroidism	Hypothyroidism	2005	Present
Microdiscectomy Lumbar spine	Intervertebral disc operation	2005	Past
Herniated disc L4-L5	Intervertebral disc protrusion	2005	Past
nephrolithiasis	Nephrolithiasis	2008	Past
Hemorrhoid	Haemorrhoids	2015	Past
Lumbar radiculopathy	Lumbar radiculopathy	2019	Present
left inguinal Hernia repair	Inguinal hernia repair	AUG2019	Past
Hemorrhoidectomy	Haemorrhoid operation	JUL2020	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	08:53
2	BNT162b2	06OCT2020 (21)	09:57

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Hydronephrosis	Hydronephrosis	02OCT2020 (17)		06OCT2020 (21)		5	2
2	RENAL	Nephrolithiasis	nephrolithiasis	02OCT2020 (17)		06OCT2020 (21)		5	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	N	Resolved (06OCT2020)	NOT RELATED/OTHER: Nephrolithiasis	1	17	N
2	TC/TCN	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: Intercurrent illness	1	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	02SEP2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	09SEP2020	
Completed	VACCINATION	05NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1953	67	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	78.18 kg	25.4 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
depression	Depression	1996	Present
attention deficit disorder	Attention deficit hyperactivity disorder	2000	Present
hypertension	Hypertension	2008	Present
insomnia	Insomnia	2010	Present
neck pain	Neck pain	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	12:31
2	BNT162b2	15SEP2020 (22)	13:55

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Aortic dilatation	Ascending aorta ectasia	10OCT2020 (47)		ONGOING			1
2	GENRL	Injection site pain	injection site tenderness	25AUG2020 (1)	19:00	26AUG2020 (2)	12:00	2	1
3	CARD	Left ventricular dysfunction	Diastolic dysfunction of the left ventricle	11OCT2020 (48)		ONGOING			1
4	NERV	Transient global amnesia	transient global amnesia	10OCT2020 (47)		10OCT2020 (47)		1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: Unknown, possibly hypertension	2	26	N
2	N	N	Resolved (26AUG2020)	Study Treatment	1	1	N
3	N	N	Yes	NOT RELATED/OTHER: Unknown, possibly hypertension	2	27	N
4	N	Y	Resolved (10OCT2020)	NOT RELATED/OTHER: unknown	2	26	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	13OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1940	79	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166.37 cm	86.82 kg	31.3 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
sulfa allergy	Drug hypersensitivity	1945	Present
Endometriosis	Endometriosis	1977	Past
codeine allergy	Drug hypersensitivity	1985	Present
tetracycline allergy	Drug hypersensitivity	1985	Present
hysterectomy	Hysterectomy	1987	Past
diverticulitis	Diverticulitis	1989	Past
Diabetes Type II	Type 2 diabetes mellitus	1990	Present
colon resection	Colectomy	1991	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
esophageal reflux	Gastrooesophageal reflux disease	2017	Present
hypercholesterolemia	Hypercholesterolaemia	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	14:35
2	BNT162b2	16SEP2020 (22)	13:27

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Nephrolithiasis	Kidney stone, worsening	03OCT2020 (39)		16OCT2020 (52)		14	3
2	RENAL	Nephrolithiasis	kidney stones	19SEP2020 (25)	14:00	23SEP2020 (29)		5	3
3	INFEC	Pyelonephritis	Pyelonephritis	03OCT2020 (39)		30OCT2020 (66)		28	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (16OCT2020)	NOT RELATED/OTHER: Supersaturated urine	2	18	N

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Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	TC	Y	Resolved (23SEP2020)	NOT RELATED/OTHER: unknown	2	4	Y
3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: Renal stone	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.1 cm	104.55 kg	38.3 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	1970	Present
sulfa allergy	Drug hypersensitivity	1970	Present
post menopausal	Postmenopause	2005	Present
bipolar disorder	Bipolar disorder	2010	Present
Depression	Depression	2011	Present
attention deficit disorder	Attention deficit hyperactivity disorder	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	11:01
2	Placebo	21SEP2020 (22)	10:41

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Salivary gland calculus	salivary gland stone	20SEP2020 (21)	18:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	TC	Y	Yes	NOT RELATED/OTHER: Salivary stone	1	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	115.64 kg	38.7 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	2015	Present
diabetes type II	Type 2 diabetes mellitus	FEB2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10SEP2020 (1)	10:55
2	Placebo	29SEP2020 (20)	13:40

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Coronary artery disease	vascular disease (coronary artery disease)	08OCT2020 (29)		ONGOING			3	TC
2	CARD	Myocardial infarction	Myocardial infarction	08OCT2020 (29)	18:00	19OCT2020 (40)		12	3	N
3	RENAL	Nocturia	nocturia	10SEP2020 (1)	22:00	12SEP2020 (3)		3	1	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Yes	NOT RELATED/OTHER: atherosclerosis	2	10	N
2	Y	Resolved (19OCT2020)	NOT RELATED/OTHER: vascular disease (coronary artery disease)	2	10	Y
3	N	Resolved (12SEP2020)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	92.27 kg	30.9 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypertension	Hypertension	2010	Present
basal cell cancer, right eye lid	Basal cell carcinoma	MAR2020	Past
basal cell excision, right eye lid	Skin lesion removal	MAR2020	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14SEP2020 (1)	13:47
2	BNT162b2	05OCT2020 (22)	12:40

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholecystitis	cholecystitis	09OCT2020 (26)		12OCT2020 (29)		4
2	HEPAT	Cholelithiasis	cholelithiasis (gallstones)	09OCT2020 (26)		11OCT2020 (28)		3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (12OCT2020)	NOT RELATED/OTHER: gallstones	2	5	Y
2	3	TC/TCN	N	Resolved (11OCT2020)	NOT RELATED/OTHER: Bile	2	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	20OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	02NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
186 cm	145 kg	41.9 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Pollinosis	Seasonal allergy	01JUL2000	Present
Osteochondrosis	Osteochondrosis	03APR2001	Present
Anxiety disorder	Anxiety disorder	MAY2001	Present
Splay-flat feet	Foot deformity	2002	Present
Depression	Depression	JAN2004	Present
irritable bowel	Irritable bowel syndrome	24AUG2010	Present
Lumbal spine syndrome	Spinal disorder	13OCT2014	Present
fatty liver	Hepatic steatosis	21NOV2014	Present
herniated disc cervical vertebra	Intervertebral disc protrusion	05OCT2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	08:17
2	Placebo	04NOV2020 (20)	08:05

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	MUSC	Intervertebral disc protrusion	herniated disc cervical vertebra	11NOV2020 (27)	13:39	ONGOING			1	N

Adverse Events					
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Yes	NOT RELATED/OTHER: surgery is necessary for diagnosed herniated disc on 05Oct2020	2	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16OCT2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1983	37	American Indian or Alaska	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	118.4 kg	36.5 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Uveitis	Uveitis	JAN2006	Present
Chronic intermittent back pain	Back pain	2012	Present
Seasonal allergies	Seasonal allergy	2012	Present
Syphilis	Syphilis	2013	Past
Foot fracture	Foot fracture	2014	Past
Surgical revision of scar tissue in foot	Scar excision	2014	Past
Anxiety	Anxiety	JUN2016	Past
Syphilis	Syphilis	MAR2020	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	15:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Abscess jaw	Abscess in left jaw	31OCT2020 (16)		ONGOING		
2	INFEC	Meningitis bacterial	Meningitis Bacterial	10NOV2020 (26)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	N	Yes	NOT RELATED/OTHER: Inflammation vs. infection	1	16	N
2	3	TC	Y	Yes	NOT RELATED/OTHER: Bacterial infection	1	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1935	84	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	81.64 kg	27.3 kg/m2	02SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arthritis	Arthritis	2018	Present
atrial fibrillation	Atrial fibrillation	2018	Present
chronic kidney isease	Chronic kidney disease	2018	Present
coronary artery disease	Coronary artery disease	2018	Present
hyperlipidemia	Hyperlipidaemia	2018	Present
hypertension	Hypertension	2018	Present
hypothyroidism	Hypothyroidism	2018	Present
history of prostate cancer	Prostate cancer	2018	Present
vitamin D deficiency	Vitamin D deficiency	2018	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	02SEP2020 (1)	19:16
2	Placebo	25SEP2020 (24)	16:20

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Asthenia	Generalized Weakness	12NOV2020 (72)	15:00	ONGOING		
2	GASTR	Constipation	intermittent constipation	28OCT2020 (57)	00:00	29OCT2020 (58)	00:00	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: COVID 19	2	49	Y
2	1	TC	N	Resolved (29OCT2020)	NOT RELATED/OTHER: diet	2	34	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccine	INFLUENZA VACCINE	28OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	02SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1947	73	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	50.3 kg	21.2 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Osteoarthritis	Osteoarthritis	1996	Present
Menopause	Menopause	1998	Present
GERD	Gastrooesophageal reflux disease	2002	Present
Melanoma	Malignant melanoma	2007	Past
Hypertension	Hypertension	2008	Present
Dyslipidemia	Dyslipidaemia	2014	Present
Hypothyroidism	Hypothyroidism	2014	Present
Eustachian Tube Dysfunction	Eustachian tube dysfunction	2017	Present
Cardiovascular prevention	Prophylaxis	2018	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Irritable bowl syndrome	Irritable bowel syndrome	2019	Present
Osteoporosis	Osteoporosis	2019	Present
Monoclonal Gammopathy of Unknown Significance	Hypergammaglobulinaemia benign monoclonal	17AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	10SEP2020 (1)	15:26
2	BNT162b2	01OCT2020 (22)	15:36

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Pancreatic mass	Mass at Pancreatic Head	05NOV2020 (57)	11:21	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: New development of pancreatic mass	2	36	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1978	42	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	125.7 kg	38.8 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetes Mellitus	Diabetes mellitus	2014	Present
Gout	Gout	2014	Present
hypertension	Hypertension	2015	Present
Cerebellar Stroke	Cerebellar stroke	2017	Past
Chronic Kidney Disease	Chronic kidney disease	2018	Present
Depression	Depression	2018	Present
Sleep Apnea	Sleep apnoea syndrome	2018	Present
glaucoma	Glaucoma	2019	Present
left frontal stroke	Cerebrovascular accident	JAN2019	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14SEP2020 (1)	12:56
2	BNT162b2	07OCT2020 (24)	15:22

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	METAB	Gout	exacerbation of gout in shoulder	04OCT2020 (21)	08:00	ONGOING			1
2	VASC	Hypertensive urgency	hypertensive urgency	28OCT2020 (45)	22:00	05NOV2020 (53)	03:40	9	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: food and medical history	1	21	N
2	TC	Y	Resolved (05NOV2020)	NOT RELATED/OTHER: hypertension	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1936	83	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	78.4 kg	27.5 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
dislocated shoulder	Joint dislocation	1966	Past
atrial fibrillation	Atrial fibrillation	1998	Present
gastroesophageal reflux	Gastrooesophageal reflux disease	2001	Present
Hypertension	Hypertension	2001	Present
sleep apnea	Sleep apnoea syndrome	2012	Present
barrett's Esophagitus	Barrett's oesophagus	2017	Present
Benign Prostatic Hypertrophy	Benign prostatic hyperplasia	2017	Present
diverticulitis	Diverticulitis	2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	13:36
2	BNT162b2	09OCT2020 (24)	11:03

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Abscess intestinal	Pericolonic Abscess	13OCT2020 (28)	19:00	ONGOING			4	TC/TCN
2	INFEC	Diverticulitis	progression of diverticulitis	29SEP2020 (14)	13:00	ONGOING			3	TC

Adverse Events					
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Yes	NOT RELATED/OTHER: related to an underlying condition reported in Medical History	2	5	Y
2	Y	Yes	NOT RELATED/OTHER: History of diverticulitis	1	14	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1984	35	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164.2 cm	64.5 kg	23.9 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	2002	Present
Renal lithiasis	Nephrolithiasis	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10AUG2020 (1)	12:00
2	Placebo	01SEP2020 (23)	14:00

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Injection site pain	PAIN AT INJECTION SITE	02SEP2020 (24)		02SEP2020 (24)		1	1	N	N
2	RENAL	Nephrolithiasis	Worsening of nephrolithiasis	09NOV2020 (92)	21:00	11NOV2020 (94)		3	3	TC	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (02SEP2020)	Study Treatment	2	2	N
2	Resolved (11NOV2020)	NOT RELATED/OTHER: Renal lithiasis (previous renal calculus migration)	2	70	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	10AUG2020	
Completed	VACCINATION	30SEP2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	52	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173.5 cm	97.3 kg	32.3 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	2000	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	12AUG2020 (1)	12:28
2	Placebo	03SEP2020 (23)	09:30

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Fall	Bicycle fall	20SEP2020 (40)		20SEP2020 (40)		1
2	INJ&P	Forearm fracture	Right forearm fracture	20SEP2020 (40)	14:00	29SEP2020 (49)		10

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TCN	N	Resolved (20SEP2020)	NOT RELATED/OTHER: accidental cause	2	18	N
2	3	TC/TCN	Y	Resolved (29SEP2020)	NOT RELATED/OTHER: fall bike	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	12AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
178.3 cm	102 kg	32.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	2012	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	10:46
2	BNT162b2	10SEP2020 (23)	10:26

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INFEC	Appendicitis	Appendicitis	01OCT2020 (44)		03OCT2020 (46)		3

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN	Y	Resolved (03OCT2020)	NOT RELATED/OTHER: cause: alimentary	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	26OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	92.3 kg	30.1 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
obesity	Obesity	2000	Present
Vasectomy	Vasectomy	2015	Past
renal lithiasis	Nephrolithiasis	APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	09:39
2	BNT162b2	11SEP2020 (23)	08:44

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Conjunctivitis	Conjunctivitis	01SEP2020 (13)		07SEP2020 (19)		7	1
2	RENAL	Renal colic	Renal colic	29AUG2020 (10)	05:00	30AUG2020 (11)	12:00	2	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (07SEP2020)	NOT RELATED/OTHER: possible cause: bacterial	1	13	N
2	TC/TCN	Y	Resolved (30AUG2020)	NOT RELATED/OTHER: Renal lithiasis	1	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	68.8 kg	24.1 kg/m2	05SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05SEP2020 (1)	15:08
2	BNT162b2	25SEP2020 (21)	09:15

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Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Cervical vertebral fracture	Fracture of the fourth cervical vertebra	21OCT2020 (47)		30OCT2020 (56)		10
2	INJ&P	Contusion	Bruises in various regions of the body	21OCT2020 (47)		30OCT2020 (56)		10
3	INJ&P	Road traffic accident	hit by motorcycle	21OCT2020 (47)	18:00	21OCT2020 (47)		1
4	INJ&P	Skin abrasion	Excoriations in various regions of the body	21OCT2020 (47)		30OCT2020 (56)		10
5	INJ&P	Spinal cord injury cervical	Cervical spinal cord contusion	21OCT2020 (47)		30OCT2020 (56)		10
6	NERV	Subarachnoid haemorrhage	Subarachnoid hemorrhage	21OCT2020 (47)		30OCT2020 (56)		10
7	RENAL	Subcapsular renal haematoma	Peri-renal hematoma	21OCT2020 (47)		30OCT2020 (56)		10

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	Y
2	2	TC	N	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	N
3	3	N	Y	Resolved (21OCT2020)	NOT RELATED/OTHER: accidental	2	27	Y
4	2	TC	N	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	N
5	3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	Y
6	3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	Y
7	3	TC	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: hit by motorcycle	2	27	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	05SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	34	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	61.3 kg	21.7 kg/m2	16SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergic rhinitis	Rhinitis allergic	1995	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16SEP2020 (1)	11:33
2	BNT162b2	06OCT2020 (21)	10:20

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NEOPL	Leydig cell tumour of the testis	Leydig cell tumor in left testicle	23SEP2020 (8)		07OCT2020 (22)		15

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	Y	Resolved (07OCT2020)	NOT RELATED/OTHER: unknown cause	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16SEP2020	
Completed	VACCINATION	04NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	49	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
150.3 cm	83.3 kg	36.9 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fibromyalgia	Fibromyalgia	2015	Present
low back pain	Back pain	2018	Present
Hysterectomy	Hysterectomy	FEB2019	Past
Perforation of the uterus by IUD	Uterine perforation	FEB2019	Past
Obesity	Obesity	MAR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17SEP2020 (1)	10:04
2	BNT162b2	07OCT2020 (21)	10:12

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Idiopathic intracranial hypertension	idiopathic intracranial hypertension	22OCT2020 (36)		30OCT2020 (44)		9	3
2	GENRL	Injection site pruritus	Pruridus at the injection site	17SEP2020 (1)	18:15	20SEP2020 (4)		4	1
3	INFEC	Postoperative wound infection	surgical site infection	03NOV2020 (48)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (30OCT2020)	NOT RELATED/OTHER: idiopathic	2	16	Y
2	N	N	Resolved (20SEP2020)	Study Treatment	1	1	N
3	TC	Y	Yes	NOT RELATED/OTHER: peritoneal loin shunt	2	28	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1975	45	Multiple	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	56 kg	21.6 kg/m2	06OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral tubal ligation	Female sterilisation	2006	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	06OCT2020 (1)	11:40
2	BNT162b2	06NOV2020 (32)	10:16

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INFEC	Urinary tract infection	Urinary tract infection	18OCT2020 (13)	06:00	22OCT2020 (17)		5

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: urinary infection	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	06OCT2020	

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1944	76	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165.8 cm	73.2 kg	26.6 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Menopause	Menopause	1993	Present
hypothyroidism	Hypothyroidism	OCT1999	Present
Diabetes mellitus type 2	Type 2 diabetes mellitus	OCT2000	Present
Systemic arterial hypertension	Hypertension	OCT2005	Present
Fracture of left femur	Femur fracture	NOV2019	Past
Osteoporosis	Osteoporosis	NOV2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	16OCT2020 (1)	12:10

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Fall	fall from own height	24OCT2020 (9)		24OCT2020 (9)		1	1	N	N
2	INJ&P	Femur fracture	Fracture of the right femur	24OCT2020 (9)		29OCT2020 (14)		6	3	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (24OCT2020)	NOT RELATED/OTHER: was knocked down on the street by a dog	1	9	N
2	Resolved (29OCT2020)	NOT RELATED/OTHER: Accidental cause: patient fell after being knocked over by a dog	1	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16OCT2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	76.4 kg	24.9 kg/m2	25SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tonsillectomy	Tonsillectomy	1960	Past
Inguinal Hernia Repair	Inguinal hernia repair	1995	Past
Inguinal Hernia Repair	Inguinal hernia repair	2005	Past
Hypertension	Hypertension	2007	Present
Bilateral lens replacement	Intraocular lens implant	2010	Past
Gastric Carcinoma	Gastric cancer	OCT2014	Past
Laparotomy for tumour excision	Abdominal operation	27OCT2014	Past
Chemotherapy	Chemotherapy	FEB2015	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25SEP2020 (1)	11:21
2	BNT162b2	16OCT2020 (22)	12:02

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Penile neoplasm	Penile Intra Epithelial Neoplasia	06NOV2020 (43)	16:24	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: Neoplasia	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25SEP2020	
Completed	VACCINATION	13NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1991	29	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
154 cm	54.5 kg	23 kg/m2	14AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14AUG2020 (1)	12:55
2	Placebo	03SEP2020 (21)	09:23

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Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	Ulna fracture	Left arm olecranon fracture	17SEP2020 (35)	20:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/TCN	Y	Yes	NOT RELATED/OTHER: Car crash	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14AUG2020	
Completed	VACCINATION	30OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2000	19	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	69.2 kg	23.9 kg/m2	15AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15AUG2020 (1)	11:10
2	BNT162b2	04SEP2020 (21)	10:45

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Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	acute appendicitis	18SEP2020 (35)	09:00	06OCT2020 (53)	15:00	19
2	INV	Electrocardiogram QT prolonged	QT interval prolongation	18SEP2020 (35)	14:00	18SEP2020 (35)	20:00	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: unknown	2	15	Y
2	1	N	N	Resolved (18SEP2020)	NOT RELATED/OTHER: Unknown	2	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	70.8 kg	25.1 kg/m2	15AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15AUG2020 (1)	12:47
2	BNT162b2	03SEP2020 (20)	10:42

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Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Anaemia	anemia	25SEP2020 (42)	08:00	ONGOING			2
2	NEOPL	Malignant melanoma	Pigmented ephitelioid melanoma of the vagina	25SEP2020 (42)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: probable relationship with vaginal tumor under study	2	23	N
2	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1974	45	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
161 cm	86.25 kg	33.3 kg/m2	15AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	15AUG2020 (1)	14:55
2	Placebo	04SEP2020 (21)	16:20

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Influenza like illness	Flu like syndrome	20AUG2020 (6)	20:00	22AUG2020 (8)	00:00	3
2	INFEC	Urinary tract infection	high urinary infection	20AUG2020 (6)	10:00	29OCT2020 (76)	08:00	71
3	GASTR	Vomiting	Vomiting	29AUG2020 (15)	08:30	01SEP2020 (18)	23:00	4

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	N	Y	Resolved (22AUG2020)	NOT RELATED/OTHER: unknown	1	6	Y
2	2	TC	N	Resolved (29OCT2020)	NOT RELATED/OTHER: unknown	1	6	N
3	1	N	N	Resolved (01SEP2020)	NOT RELATED/OTHER: unknown	1	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15AUG2020	
Completed	VACCINATION	02OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	68.6 kg	24.6 kg/m2	16AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16AUG2020 (1)	14:36
2	BNT162b2	07SEP2020 (23)	13:47

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Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Gastritis	Acute gastritis	17OCT2020 (63)	10:00	03NOV2020 (80)	10:00	18
2	INJ&P	Hand fracture	closed fracture first phalanx right little finger	14SEP2020 (30)	19:30	15OCT2020 (61)	11:57	32

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (03NOV2020)	NOT RELATED/OTHER: unknown	2	41	Y
2	1	TC/TCN	N	Resolved (15OCT2020)	NOT RELATED/OTHER: hit with a clay pot	2	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	16AUG2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1967	52	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	63.5 kg	23.6 kg/m2	17AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	11:10
2	Placebo	07SEP2020 (22)	12:45

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INFEC	Urosepsis	Urosepsis	15SEP2020 (30)	16:00	22SEP2020 (37)	17:00	8

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (22SEP2020)	NOT RELATED/OTHER: unknown	2	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	06OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
157 cm	99.5 kg	40.4 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
laparoscopic cholecystectomy	Cholecystectomy	APR2011	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17AUG2020 (1)	13:39
2	BNT162b2	07SEP2020 (22)	16:35

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	HEPAT	Biliary colic	biliary colic	30OCT2020 (75)	19:00	03NOV2020 (79)	11:00	5

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (03NOV2020)	NOT RELATED/OTHER: unknown	2	54	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1965	55	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	78.85 kg	26.3 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Colon Cancer	Colon cancer	03APR2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	17:46
2	Placebo	07SEP2020 (22)	14:15

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Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Foot fracture	Hallux fracture and second toe of the right foot	16SEP2020 (31)	08:00	20OCT2020 (65)	19:00	35

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (20OCT2020)	NOT RELATED/OTHER: work accident	2	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1992	27	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	70 kg	24.2 kg/m2	17AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypothyroidism	Hypothyroidism	01JUL2000	Present
Diabetes type 1	Type 1 diabetes mellitus	01JUL2011	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17AUG2020 (1)	18:10
2	Placebo	07SEP2020 (22)	14:13

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	METAB	Hypoglycaemia	severe hipoglycemia	16OCT2020 (61)	15:30	16OCT2020 (61)	15:35	1
2	NERV	Seizure	seizure	16OCT2020 (61)	15:30	16OCT2020 (61)	15:35	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Resolved (16OCT2020)	NOT RELATED/OTHER: Diabetes type 1	2	40	Y
2	3	N	N	Resolved (16OCT2020)	NOT RELATED/OTHER: hypoglycemia	2	40	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17AUG2020	
Completed	VACCINATION	05OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1952	68	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	68 kg	24.1 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
arterial hypertension	Hypertension	02JUL2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18AUG2020 (1)	12:19
2	Placebo	08SEP2020 (22)	14:55

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Syncope	Syncope	11SEP2020 (25)	10:00	12SEP2020 (26)	15:00	2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (12SEP2020)	NOT RELATED/OTHER: unknown	2	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1995	25	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170 cm	110 kg	38.1 kg/m2	19AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	19AUG2020 (1)	17:56
2	BNT162b2	09SEP2020 (22)	10:55

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Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Osteochondritis	Osteochondritis	05SEP2020 (18)	12:00	06SEP2020 (19)	13:31	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	Y	Resolved (06SEP2020)	NOT RELATED/OTHER: unknown	1	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	19AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1996	24	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	59.5 kg	23.2 kg/m2	20AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	20AUG2020 (1)	14:05
2	Placebo	09SEP2020 (21)	14:05

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	HEPAT	Cholelithiasis	Gallstones	06NOV2020 (79)	08:00	08NOV2020 (81)	13:30	3	1
2	RENAL	Hydronephrosis	Right hydronephrosis	05NOV2020 (78)	20:30	ONGOING			2
3	RENAL	Renal colic	Renal colic	20OCT2020 (62)	10:00	20OCT2020 (62)	12:00	1	2
4	RENAL	Renal colic	Renal colic	05NOV2020 (78)	20:30	ONGOING			3

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (08NOV2020)	NOT RELATED/OTHER: Unknown	2	59	N
2	TC	N	Yes	NOT RELATED/OTHER: Renal colic	2	58	N
3	TC	N	Resolved (20OCT2020)	NOT RELATED/OTHER: Unknown	2	42	N
4	TC	Y	Yes	NOT RELATED/OTHER: Renal colic in october 2020.	2	58	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184 cm	119.45 kg	35.3 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
OBESITY	Obesity	09APR2002	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20AUG2020 (1)	15:15
2	BNT162b2	11SEP2020 (23)	18:25

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Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute coronary syndrome	Acute coronary syndrome without ST-T segment elevation	16SEP2020 (28)	09:15	19SEP2020 (31)	14:00	4	2
2	CARD	Bundle branch block right	right bundle branch block	16SEP2020 (28)	15:20	19SEP2020 (31)	14:00	4	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (19SEP2020)	NOT RELATED/OTHER: unknown	2	6	Y
2	N	N	Resolved (19SEP2020)	NOT RELATED/OTHER: Acute coronary syndrome	2	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1976	44	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	149 kg	50.4 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sleep apnea	Sleep apnoea syndrome	01JAN2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21AUG2020 (1)	13:20
2	BNT162b2	11SEP2020 (22)	10:50

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Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Arrhythmia supraventricular	Arrhythmia supraventricular	17SEP2020 (28)	11:00	19SEP2020 (30)	10:00	3	4	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (19SEP2020)	NOT RELATED/OTHER: unknown, but probably corresponds to an accessory intraventricular line	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162 cm	70.8 kg	27 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	13:40
2	Placebo	08OCT2020 (49)	11:26

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Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Craniocerebral injury	minor cranioencephalic trauma	08OCT2020 (49)	12:18	08OCT2020 (49)	12:18	1	1	N	N
2	NERV	Syncope	syncope	08OCT2020 (49)	12:18	08OCT2020 (49)	14:06	1	3	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (08OCT2020)	NOT RELATED/OTHER: Head trauma due to fall from own height after syncope	2	1	N
2	Resolved (08OCT2020)	NOT RELATED/OTHER: syncope of probable vasogenic cause	2	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	11NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	103 kg	35.2 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	16:00
2	Placebo	14SEP2020 (25)	11:00

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Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	CARD	Atrioventricular block second degree	Second degree AV block (Mobitz II)	10NOV2020 (82)	10:00	ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		2	N	Y	Yes	NOT RELATED/OTHER: unknown	2	58	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	16OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	52.05 kg	18.7 kg/m2	22AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
intermittent gross hematuria	Haematuria	JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22AUG2020 (1)	14:40
2	Placebo	10SEP2020 (20)	15:35

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	RENAL	Haematuria	haematuria	25AUG2020 (4)	14:00	22SEP2020 (32)	08:00	29
2	RENAL	Urinary bladder polyp	Bladder polyp	18SEP2020 (28)	08:00	ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (22SEP2020)	NOT RELATED/OTHER: Bladder polyp	1	4	N
2	1	TCN	Y	Yes	NOT RELATED/OTHER: Unknow.	2	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	22AUG2020	
Completed	VACCINATION	09OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	65	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	63 kg	23.7 kg/m2	24AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	16:09
2	Placebo	15SEP2020 (23)	15:17

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Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	RESP	Pulmonary mass	Right pulmonary nodule	24SEP2020 (32)	17:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Withdrawn	VACCINATION	26OCT2020	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	26OCT2020	WITHDRAWAL BY SUBJECT

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	54	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152 cm	71.5 kg	30.9 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bronchial asthma	Asthma	1967	Present
Hypothyroidism	Hypothyroidism	01JUN1995	Present
low back pain	Back pain	2005	Present
bilteral pleural effusion	Pleural effusion	15APR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	24AUG2020 (1)	17:00
2	Placebo	13SEP2020 (21)	18:40

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Ischaemic stroke	Ischemic Stroke	06NOV2020 (75)	23:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	N	Y	Yes	NOT RELATED/OTHER: unknown	2	55	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	13OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	66 kg	23.7 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sjogren syndrome	Sjogren's syndrome	07JUL1977	Present
insomnia	Insomnia	07JUL1990	Present
Right hip replacement surgery	Hip arthroplasty	19DEC2018	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	17:45
2	BNT162b2	13SEP2020 (21)	15:58

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Emphysema	Panlobar emphysema	09OCT2020 (47)		ONGOING			1
2	RESP	Pneumonitis	Non-specific Pneumonitis	29SEP2020 (37)	15:30	ONGOING			2
3	INFEC	Sialoadenitis	Left submaxillary sialadenitis	03NOV2020 (72)	08:00	09NOV2020 (78)	20:00	7	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: Unknown	2	27	N
2	N	Y	Yes	NOT RELATED/OTHER: unknown	2	17	Y
3	TC	N	Resolved (09NOV2020)	NOT RELATED/OTHER: Sjogren's syndrome	2	52	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	88 kg	29.1 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Kidney stones	Nephrolithiasis	01JAN1961	Present
Irritable colon	Irritable bowel syndrome	01JAN2005	Present
Arterial hypertension	Hypertension	2012	Present
L4-L5 disc herniation	Intervertebral disc protrusion	DEC2013	Present
Surgical placement of interspinous spacer at L4-L5	Spinal operation	06DEC2013	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	24AUG2020 (1)	20:55
2	BNT162b2	14SEP2020 (22)	20:05

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	MUSC	Intervertebral disc protrusion	Worsening lumbar disc herniation	10SEP2020 (18)	10:00	12NOV2020 (81)	15:00	64	3	TC/TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (12NOV2020)	NOT RELATED/OTHER: Unresolved chronic lumbar disc herniation. spinal surgery performed in 2013	1	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	24AUG2020	
Completed	VACCINATION	12OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	72 kg	27.1 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypothyroidism	Hypothyroidism	25AUG2010	Present
bilateral oophorectomy	Oophorectomy bilateral	OCT2014	Past
Bilateral adnexal cysts	Adnexa uteri cyst	07OCT2014	Past
Bilateral adnexectomy	Salpingo-oophorectomy bilateral	21OCT2014	Past
allergic rhinitis	Rhinitis allergic	2015	Present
asthma	Asthma	01APR2019	Present
hospitalization for asthmatic crisis	Asthmatic crisis	01JUL2019	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	17:05
2	BNT162b2	15SEP2020 (22)	18:38

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	CARD	Acute coronary syndrome	Acute coronary syndrome	08NOV2020 (76)	17:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	2	55	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	19OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	Not Reported	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	79.15 kg	28.7 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Heavy Smoking	Tobacco user	1975	Past
Gastroduodenal Bleeding Ulcer	Gastrointestinal ulcer haemorrhage	1998	Past
Diverticulitis	Diverticulitis	01APR2018	Past
Colon Resection	Colectomy	15APR2018	Past
Dyslipemia	Dyslipidaemia	SEP2018	Present
Acute myocardial infarction	Acute myocardial infarction	21SEP2018	Past
angioplasty with stent placement	Vascular stent insertion	21SEP2018	Past
Arterial Hypertension	Hypertension	23SEP2018	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	18:45
2	BNT162b2	14SEP2020 (21)	16:25

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Angina pectoris	Angina Pectoris	20SEP2020 (27)	17:00	24SEP2020 (31)	08:30	5
2	PSYCH	Anxiety	Anxiety Crysis	29SEP2020 (36)	12:00	29SEP2020 (36)	18:30	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (24SEP2020)	NOT RELATED/OTHER: coronary disease	2	7	Y
2	2	N	N	Resolved (29SEP2020)	NOT RELATED/OTHER: Angina Pectoris	2	16	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	25AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	57	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163 cm	91 kg	34.3 kg/m2	26AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	26AUG2020 (1)	14:50

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Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Appendicitis	Acute Appendicitis	05SEP2020 (11)	22:00	09SEP2020 (15)	14:00	5	3
2	VASC	Orthostatic hypotension	orthostatic hypotension	11OCT2020 (47)	06:30	12OCT2020 (48)	13:00	2	1
3	EAR	Vertigo	Vertigo	07OCT2020 (43)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: unknown	1	11	Y
2	N	N	Resolved (12OCT2020)	NOT RELATED/OTHER: dietary habit change, lower intake.	1	47	N
3	N	N	Yes	NOT RELATED/OTHER: Unknow	1	43	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	26AUG2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1994	26	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
165 cm	64 kg	23.5 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Dengue	Dengue fever	15APR2020	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	27AUG2020 (1)	11:05
2	Placebo	16SEP2020 (21)	14:20

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	RESP	Epistaxis	Epistaxis	20SEP2020 (25)	19:30	19OCT2020 (54)	22:00	30
2	INJ&P	Multiple injuries	Polytrauma	20SEP2020 (25)	19:30	ONGOING		
3	VASC	Subgaleal haematoma	subgaleal hematoma	20SEP2020 (25)	19:30	ONGOING		

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TCN	N	Resolved (19OCT2020)	NOT RELATED/OTHER: sphenoid fracture	2	5	N
2	3	TC/TCN	Y	Yes	NOT RELATED/OTHER: Hit by a vehicle	2	5	Y
3	2	TCN	N	Yes	NOT RELATED/OTHER: road accident	2	5	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
166 cm	70 kg	25.4 kg/m2	28AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	14:15
2	Placebo	18SEP2020 (22)	15:00

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	INFEC	Abdominal abscess	Intra-abdominal Abscess	29OCT2020 (63)	12:00	ONGOING			3	TC/TCN	Y
2	INFEC	Appendicitis	appendicitis	16OCT2020 (50)	09:00	24OCT2020 (58)	14:00	9	3	TC/TCN	Y

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: surgical history of appendicitis on 19OCT2020	2	42	Y
2	Resolved (24OCT2020)	NOT RELATED/OTHER: Unknown	2	29	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1963	56	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	98 kg	32 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
intermittent asthma	Asthma	(b) (6) 1963	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	28AUG2020 (1)	17:50
2	Placebo	16SEP2020 (20)	11:30

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INFEC	Pneumonia	community acquired pneumonia	03OCT2020 (37)	21:00	15OCT2020 (49)	21:03	13

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN	Y	Resolved (15OCT2020)	NOT RELATED/OTHER: unknown	2	18	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	61.2 kg	22.8 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Amblyopia of the right eye	Amblyopia	(b) (6) 1968	Present
Left hemicrania migraine	Migraine	01JUN1977	Present
allergic to penicillin	Drug hypersensitivity	26AUG1977	Present
Myopia of the left eye	Myopia	01JAN1986	Present
Depression and anxiety	Depression	01JUN2005	Past
Herpes zoster	Herpes zoster	28DEC2016	Present

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Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	29AUG2020 (1)	16:31
2	BNT162b2	17SEP2020 (20)	16:05

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	EYE	Choroidal neovascularisation	Myopic choroidal neovascular membrane of the left eye	06SEP2020 (9)	17:00	ONGOING			2	N	Y

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: Complication of high myopia presented by the voluntary as antecedent	1	9	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	29AUG2020	
Completed	VACCINATION	21OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	125 kg	41.3 kg/m2	30AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Congenital ocular toxoplasmosis	Congenital toxoplasmosis	(b) (6) 1970	Past
Heavy Smoking	Tobacco user	03MAR1986	Past
Obesity	Obesity	1992	Present
ANGIOPLASTY	Angioplasty	JAN2015	Past
STENT PLACEMENT	Stent placement	JAN2015	Past
Myocardial infarction	Myocardial infarction	18JAN2015	Past
Arterial hypertension	Hypertension	19AUG2015	Present
Dyslipidemia	Dyslipidaemia	20AUG2015	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30AUG2020 (1)	12:25
2	BNT162b2	19SEP2020 (21)	09:56

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Angina unstable	Unstable Angina Pectoris	14OCT2020 (46)	18:00	16OCT2020 (48)	11:00	3	3	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (16OCT2020)	NOT RELATED/OTHER: Unknown cause, history of acute myocardial infarction	2	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	30AUG2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1954	66	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
174 cm	78.5 kg	25.9 kg/m2	31AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31AUG2020 (1)	16:26
2	BNT162b2	19SEP2020 (20)	14:50

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Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GASTR	Gastrooesophageal reflux disease	Gastroesophageal reflux disease	30OCT2020 (61)	08:00	ONGOING	
2	INFEC	Suspected COVID-19	Probable COVID-19 illnes	17OCT2020 (48)	09:00	ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		2	TC	N	Yes	NOT RELATED/OTHER: Unknown	2	42	N
2		4	TC	Y	Yes	NOT RELATED/OTHER: unknown	2	29	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1959	60	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
179 cm	128 kg	39.9 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
RIGHT DEAF	Deafness unilateral	01JUL1960	Present
arterial hypertension	Hypertension	01JAN2005	Present
OBESITY	Obesity	01JUL2005	Present
Glaucoma in both eyes	Glaucoma	01JUL2017	Present
ISOLATED HEMATOCHESIS	Haematochezia	15AUG2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	31AUG2020 (1)	17:10
2	Placebo	19SEP2020 (20)	15:55

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Ischaemic stroke	Ischemic stroke	12OCT2020 (43)	17:00	16OCT2020 (47)	17:30	5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Resolved (16OCT2020)	NOT RELATED/OTHER: unknown	2	24	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	14NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1982	38	Multiple	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.5 cm	55.5 kg	23.9 kg/m2	18AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Breast lump	Breast mass	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18AUG2020 (1)	09:26
2	BNT162b2	09SEP2020 (23)	10:33

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Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	REPRO	Breast hyperplasia	Atypical intraductal hyperplasia in left breast	29SEP2020 (43)		30SEP2020 (44)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Resolved (30SEP2020)	NOT RELATED/OTHER: Breast nodule	2	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	18AUG2020	
Completed	VACCINATION	07OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1962	58	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155.5 cm	67.9 kg	28.1 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Carpal tunnel syndrome	Carpal tunnel syndrome	2013	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	18:32
2	BNT162b2	24SEP2020 (21)	09:34

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Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	HEPAT	Cholecystitis	Acute cholecystitis with cholelithiasis	24OCT2020 (51)		28OCT2020 (55)		5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (28OCT2020)	NOT RELATED/OTHER: gallstone	2	31	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	22OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	Multiple	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	81.3 kg	28.5 kg/m2	17SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Systemic arterial hypertension	Hypertension	DEC2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	17SEP2020 (1)	15:31
2	BNT162b2	08OCT2020 (22)	16:14

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Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	BLOOD	Hypochromic anaemia	HYPOCHROMIC ANEMIA / MICROCYTIC	04NOV2020 (49)		ONGOING			1	N
2	INFEC	Pyelonephritis acute	ACUTE PYELINEPHRITIS	02NOV2020 (47)		ONGOING			2	TC

Adverse Events

AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Yes	NOT RELATED/OTHER: ANEMIA TO BE CLARIFIED	2	28	N
2	Y	Yes	NOT RELATED/OTHER: POSSIBLE BACTERIA URINARY TRACT INFECTION	2	26	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	17SEP2020	
Completed	VACCINATION	09NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1955	65	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	78.5 kg	28.8 kg/m2	15OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Chronic tension headache	Tension headache	1970	Present
Hemorrhoidal disease	Haemorrhoids	1980	Present
gastroesophageal reflux disease	Gastrooesophageal reflux disease	2000	Present
Systemic arterial hypertension	Hypertension	2005	Present
Allergic rhinitis	Rhinitis allergic	2005	Present
carotid atherosclerotic disease	Carotid arteriosclerosis	2015	Present
dyslipidemia	Dyslipidaemia	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15OCT2020 (1)	08:54
2	BNT162b2	06NOV2020 (23)	09:22

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PSYCH	Disorientation	Disorientation to clarify	09NOV2020 (26)		12NOV2020 (29)		4

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (12NOV2020)	NOT RELATED/OTHER: to clarify	2	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	15OCT2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1961	59	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
164 cm	87.05 kg	32.4 kg/m2	29SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Allergy Penicillin	Drug hypersensitivity	1964	Present
Allergy sulfas	Drug hypersensitivity	1964	Present
Hypertension	Hypertension	2008	Present
Vasectomy	Vasectomy	2012	Past
Intermittent headache	Headache	MAY2016	Present
Vision impairment	Visual impairment	MAY2017	Present
Hypercholesterolemia	Hypercholesterolaemia	DEC2018	Present
Depression-stable	Depression	AUG2019	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29SEP2020 (1)	10:40
2	BNT162b2	20OCT2020 (22)	13:11

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Chest pain	Chest pain	10NOV2020 (43)		12NOV2020 (45)		3	3	TCN	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (12NOV2020)	NOT RELATED/OTHER: Hypercholesterolemia and hypertension medical history	2	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	29SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1945	74	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180 cm	119.3 kg	36.8 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Penicillin/Sulfa Hives	Urticaria	2010	Present
Stroke	Cerebrovascular accident	2014	Present
Arthritis	Arthritis	2015	Present
Hypertension	Hypertension	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	15:41
2	Placebo	21OCT2020 (41)	13:13

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Cerebrovascular accident	Mild Stroke	23SEP2020 (13)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Yes	NOT RELATED/OTHER: Atherosclerotic cardiovascular disease	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
	VACCINATION		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1946	74	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
158.5 cm	56.2 kg	22.4 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
High Cholesterol	Blood cholesterol increased	2015	Present
Seasonal Allergy	Seasonal allergy	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	16:38
2	Placebo	05OCT2020 (22)	14:47

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Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Brain abscess	Brain abscess	10OCT2020 (27)		ONGOING			4
2	NERV	Headache	Headache (R sided headache around R eye)	03OCT2020 (20)		05OCT2020 (22)		3	1
3	INFEC	Sinusitis	Sinusitis	10OCT2020 (27)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	Y	Yes	NOT RELATED/OTHER: Sinusitis / blocked sinuses	2	6	Y
2	TC	N	Resolved (05OCT2020)	NOT RELATED/OTHER: Headache	1	20	N
3	TCN	N	Yes	NOT RELATED/OTHER: Sinusitis/Blocked Sinuses	2	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1964	56	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.8 cm	105.45 kg	33.3 kg/m2	25AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Tubal Ligation	Female sterilisation	27FEB1992	Past
Chronic Hepatitis C	Chronic hepatitis C	2009	Present
Hypertension	Hypertension	2010	Present
depression	Depression	2018	Present
Post menopausal	Postmenopause	17OCT2018	Present
R Ankle pain	Arthralgia	MAR2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	25AUG2020 (1)	09:40

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Hypertension	exacerbation of hypertension	04SEP2020 (11)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Yes	NOT RELATED/OTHER: environmental factors, psychiatric factors	1	11	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	25AUG2020	
Withdrawn	VACCINATION	03NOV2020	PHYSICIAN DECISION
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171.45 cm	69.18 kg	23.5 kg/m2	01SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
colon cancer	Colon cancer	2010	Past
S/P Colostomy	Colostomy	2010	Past
Hyperlipidemia	Hyperlipidaemia	2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	01SEP2020 (1)	10:23
2	BNT162b2	22SEP2020 (22)	09:23

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Injection site pain	Soreness at injection site	23SEP2020 (23)	03:30	24SEP2020 (24)	08:00	2	1
2	GENRL	Injection site pain	soreness at injection site	02SEP2020 (2)	04:00	04SEP2020 (4)	04:00	3	1
3	GASTR	Small intestinal obstruction	small bowel obstruction	29OCT2020 (59)		05NOV2020 (66)		8	3

Adverse Events						
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (24SEP2020)	Study Treatment	2	2	N
2	N	N	Resolved (04SEP2020)	Study Treatment	1	2	N
3	TC/TCN	Y	Resolved (05NOV2020)	NOT RELATED/OTHER: small bowel obstruction	2	38	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	01SEP2020	
Completed	VACCINATION	20OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1949	71	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167 cm	96.3 kg	34.5 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Former tobacco smoker	Ex-tobacco user	1965	Past
hypercholesteromia	Hypercholesterolaemia	2005	Present
hypertension	Hypertension	2005	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	04SEP2020 (1)	15:41
2	Placebo	24SEP2020 (21)	13:32

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Aortic aneurysm	abdominal aortic aneurysm	07OCT2020 (34)	01:09	ONGOING			2
2	INFEC	Appendicitis	acute appendicitis	05OCT2020 (32)		07OCT2020 (34)		3	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: incidential finding on CT scan	2	14	N
2	TC/TCN	Y	Resolved (07OCT2020)	NOT RELATED/OTHER: appendicitis	2	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
influenza vaccination	INFLUENZA VACCINE	07OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	27OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	92.9 kg	32.9 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hydrocele Repair	Hydrocele operation	15JUN2009	Past
vasectomy	Vasectomy	15JUN2013	Past
Rash to antibiotics of unclear type	Drug eruption	15JUN2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	27AUG2020 (1)	14:50
2	BNT162b2	17SEP2020 (22)	14:38

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Abscess	Lip Abscess	23SEP2020 (28)		01OCT2020 (36)		9	3
2	INFEC	Cellulitis	Lip cellulitis	23SEP2020 (28)		01OCT2020 (36)		9	3
3	GENRL	Chills	CHILLS - ADVERSE REACTION TO VACCINATION 1	28AUG2020 (2)	03:00	30AUG2020 (4)	21:00	3	1
4	IMMUN	Drug hypersensitivity	Hypersensitivity to antibiotics	26SEP2020 (31)		27SEP2020 (32)		2	3
5	NERV	Headache	HEADACHE - ADVERSE REACTION TO VACCINATION 1	28AUG2020 (2)	03:00	30AUG2020 (4)	21:00	3	1
6	MUSC	Myalgia	DIFFUSE MYALGIA - ADVERSE REACTION TO VACCINATION 1	28AUG2020 (2)	03:00	30AUG2020 (4)	21:00	3	1

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Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (01OCT2020)	NOT RELATED/OTHER: unrelated medical condition	2	7	Y
2	TC	Y	Resolved (01OCT2020)	NOT RELATED/OTHER: Unrelated medical condition	2	7	Y
3	TC	N	Resolved (30AUG2020)	Study Treatment	1	2	N
4	TC	Y	Resolved (27SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	10	Y
5	TC	N	Resolved (30AUG2020)	Study Treatment	1	2	N
6	TC	N	Resolved (30AUG2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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FDA-CBER-2021-5683-1788312

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Completed	VACCINATION	15OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1973	47	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
149.9 cm	81 kg	36 kg/m2	11SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fallopian tube ligation	Female sterilisation	1998	Past
Irritable bowel syndrome	Irritable bowel syndrome	17JUN2004	Present
Syncope and collapse	Syncope	07OCT2005	Past
Gastroesophageal reflux disease	Gastrooesophageal reflux disease	10APR2006	Present
Chronic abdominal pain	Abdominal pain	17AUG2006	Present
Fatty liver	Hepatic steatosis	18OCT2006	Present
Major depressive disorder, recurrent episode	Major depression	25JAN2007	Present
Single seizure, unspecified type	Seizure	05JUN2007	Past
Sinus tachycardia	Sinus tachycardia	05JUN2007	Past

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Fibromyalgia	Fibromyalgia	02NOV2007	Present
Drug allergy - Nexium [Esomeprazole Magnesium]	Drug hypersensitivity	17JAN2008	Present
Generalized anxiety disorder	Generalised anxiety disorder	28FEB2008	Present
Bipolar 1 disorder, mixed, moderate	Bipolar I disorder	26JAN2010	Present
Overactive bladder	Hypertonic bladder	06AUG2010	Present
Colonoscopy with biopsy	Biopsy colon	15NOV2010	Past
Obesity	Obesity	13APR2011	Present
Diabetes mellitus, type 2	Type 2 diabetes mellitus	26MAY2011	Present
Peripheral neuropathy	Neuropathy peripheral	03MAY2013	Present
Dyslipidemia	Dyslipidaemia	27JUN2013	Present
Benign fasciculation cramp syndrome	Cramp-fasciculation syndrome	30AUG2013	Present
Laparoscopic hysterectomy	Hysterectomy	12DEC2013	Past
Laparascopic salpingectomy (bilateral)	Salpingectomy	12DEC2013	Past
Chronic kidney disease, stage 2	Chronic kidney disease	11FEB2014	Present
Colonoscopy with biopsy	Biopsy colon	08JUL2014	Past
Right blepharospasm	Blepharospasm	09OCT2014	Present
Gastroparesis	Impaired gastric emptying	31DEC2014	Present
Laparascopic lysis of intra-abdominal adhesion	Adhesiolysis	15MAY2015	Past
Diagnostic laparoscopy	Laparoscopy	15MAY2015	Past
Asthma	Asthma	16AUG2016	Present
Hypertension	Hypertension	19JAN2017	Present
Chronic pancreatitis	Pancreatitis chronic	19JAN2017	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	11SEP2020 (1)	12:02
2	Placebo	30SEP2020 (20)	11:53

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain	Abdominal pain	25SEP2020 (15)		08OCT2020 (28)		14	2
2	PSYCH	Confusional state	Confusion/altered mental status	28SEP2020 (18)		29SEP2020 (19)		2	2
3	IMMUN	Hypersensitivity	Allergic reaction	30OCT2020 (50)		01NOV2020 (52)		3	1
4	METAB	Hypoglycaemia	Hypoglycemia	12SEP2020 (2)		13SEP2020 (3)		2	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (08OCT2020)	NOT RELATED/OTHER: Suspected irritable bowel syndrome	1	15	N
2	N	N	Resolved (29SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	18	N
3	TC	N	Resolved (01NOV2020)	NOT RELATED/OTHER: None	2	31	N
4	TC	Y	Resolved (13SEP2020)	NOT RELATED/CONCOMITANT DRUG TREATMENT	1	2	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flulaval Quadrivalent	INFLUENZA VACCINE INACT SPLIT 4V	22OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	11SEP2020	
Completed	VACCINATION	06NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1989	31	American Indian or Alaska	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.2 cm	107.7 kg	37.2 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Intermittent Asthma	Asthma	23MAR2017	Present
Allergic Rhinitis	Rhinitis allergic	23MAR2017	Present
Anal Skin Tag	Anal skin tags	21AUG2018	Present
Acne Vulgaris	Acne	16AUG2019	Present
Intermittent Sinus Headache	Sinus headache	25OCT2019	Present
Cyclothymic Disorder	Cyclothymic disorder	17APR2020	Present
Genital Herpes Simplex	Genital herpes simplex	30JUL2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04SEP2020 (1)	11:52
2	BNT162b2	30SEP2020 (27)	15:56

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Appendicitis	APPENDICITIS	20SEP2020 (17)	21:00	22SEP2020 (19)	10:19	3
2	INV	Blood cholesterol increased	Elevated Cholesterol	08OCT2020 (35)	18:41	ONGOING		
3	INV	Low density lipoprotein increased	Elevated Low-Density Lipoprotein	08OCT2020 (35)	18:41	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/TCN	Y	Resolved (22SEP2020)	NOT RELATED/OTHER: UNKNOWN	1	17	Y
2	1	TCN	N	Yes	NOT RELATED/OTHER: Unknown	2	9	N
3	1	TCN	N	Yes	NOT RELATED/OTHER: Unknown	2	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Flulaval Quadrivalent 2020-2021 PF (Influenza Vaccine)	INFLUENZA VACCINE INACT SPLIT 4V	28OCT2020

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	04SEP2020	
Completed	VACCINATION	28OCT2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1985	35	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
165 cm	60.4 kg	22.2 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Idiopathic thrombocytopenic purpura	Immune thrombocytopenia	01MAR2010	Past
left ovarian cyst	Ovarian cyst	10SEP2019	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	12:54
2	Placebo	04NOV2020 (45)	10:05

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	REPRO	Haemorrhagic ovarian cyst	Hemorrhagic cyst of the right ovary	21OCT2020 (31)		ONGOING			1
2	INJ&P	Procedural haemorrhage	Intraoperative hemorrhage during an elective laparoscopic ovarian cystectomy	03OCT2020 (13)	07:30	07OCT2020 (17)	10:00	5	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: Unknown	1	31	N
2	TC	Y	Resolved (07OCT2020)	NOT RELATED/OTHER: Laparoscopic surgery	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21SEP2020	
	VACCINATION		
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1966	53	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
173 cm	87.3 kg	29.2 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Type 2 diabetes	Type 2 diabetes mellitus	01MAR2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21SEP2020 (1)	20:25
2	BNT162b2	12OCT2020 (22)	10:48

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Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1			Jammed Right inguinal hernia	05OCT2020 (15)	16:00	22OCT2020 (32)	15:00	18	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: complication of right inguinal hernia	1	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Completed	VACCINATION	11NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1969	51	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
159 cm	61 kg	24.1 kg/m2	23SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Arterial hypertension	Hypertension	03SEP2014	Present
Anxiety disorder	Anxiety disorder	14SEP2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23SEP2020 (1)	17:26
2	Placebo	14OCT2020 (22)	15:42

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Oesophageal food impaction	esophageal impaction with food	28SEP2020 (6)	21:00	29SEP2020 (7)	10:30	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (29SEP2020)	NOT RELATED/OTHER: food impaction	1	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	23SEP2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	111.36 kg	32.3 kg/m2	21SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
bilateral broken ankles	Ankle fracture	2010	Past
bilateral fused ankles	Arthrodesis	2010	Past
cholecystectomy	Cholecystectomy	2010	Past
gallstones	Cholelithiasis	2010	Past
rotator cuff repair (right)	Rotator cuff repair	2010	Past
torn rotator cuff (right)	Rotator cuff syndrome	2010	Past
diabetes type II	Type 2 diabetes mellitus	2010	Present
atrial fibrillation	Atrial fibrillation	2012	Present
ace inhibitor allergy	Drug hypersensitivity	2015	Present
left knee replacement	Knee arthroplasty	2015	Past

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21SEP2020 (1)	14:10

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	21SEP2020 (1)	21SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21SEP2020 (1)	21SEP2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	Yes

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Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 14OCT2020 (24)/ 12OCT2020 (22)/ ONGOING	YES	DIARRHEA	
	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	14OCT2020 (24)	Covid-19	14OCT2020 (24)	2	COVID-19

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SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	14OCT2020 (24)	14OCT2020 (24)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	14OCT2020 (24)	SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA
		PRIMARY CARE PHYSICIAN	YES	1	NA
		OTHER	YES	1	Covid Test Center/Regional hospital

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Hospitalization Details					
Visit	**Visit Date (Study Day)**	**Hospitalization Category**	**Hospitalization Term**	**Admission Date (Study Day)**	**Discharge Date or Ongoing (Study Day)**
COVID Illness Visit 1	14OCT2020 (24)	HOSPITALIZATION STATUS	HOSPITAL	16OCT2020 (26)	ONGOING

Respiratory Treatment						
Visit	**Visit Date (Study Day)**	**Treatment Identifier**	**Prespecified Concomitant Nondrug Treatment**	**Treatment**	**Start Date (Study Day)**	**End Date or Ongoing (Study Day)**
COVID Illness Visit 1	14OCT2020 (24)	1	YES	HIGH FLOW OXYGEN THERAPY	16OCT2020 (26)	ONGOING

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

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Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	14OCT2020 (24)	16OCT2020 (26)	Creatinine	114.9	umol/L	61.9	106.1
			Urea Nitrogen	10	mmol/L	2.86	8.21
		17OCT2020 (27)	Alkaline Phosphatase	1.22	ukat/L	0.65	2.84
			Alanine Aminotransferase	0.5001	ukat/L	0.65013	0.65013
			Aspartate Aminotransferase	0.86684	ukat/L	0.70014	0.70014
			Bilirubin	6.8	umol/L	17.1	17.1
			Creatinine	114.9	umol/L	61.9	106.1
			C Reactive Protein	1.1	mg/L	0.5	0.5
			Urea Nitrogen	10.71	mmol/L	2.86	8.21
		18OCT2020 (28)	Alkaline Phosphatase	1.2	ukat/L	0.65	1.95
			Alanine Aminotransferase	0.63346	ukat/L	0.70014	0.70014
			Aspartate Aminotransferase	0.3334	ukat/L	0.65013	0.65013
			Bilirubin	5.1	umol/L	17.1	17.1
			Creatinine	88.4	umol/L	61.9	106.1
			Urea Nitrogen	8.57	mmol/L	2.86	8.21
		19OCT2020 (29)	Alkaline Phosphatase	1.12	ukat/L	0.48	1.95
			Alanine Aminotransferase	0.51677	ukat/L	0.70014	0.70014
			Aspartate Aminotransferase	0.28339	ukat/L	0.65013	0.65013
			Bilirubin	5.1	umol/L	17.1	17.1
			Creatinine	70.7	umol/L	61.9	106.1
			Urea Nitrogen	10.36	mmol/L	1.79	10
		23OCT2020 (33)	Alkaline Phosphatase	1.08	ukat/L	0.65	1.95
			Alanine Aminotransferase	0.55011	ukat/L	0.70014	0.70014
			Aspartate Aminotransferase	0.35007	ukat/L	0.65013	0.65013
			Bilirubin	5.1	umol/L	17.1	17.1

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Laboratory Results - Clinical Chemistry							
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**
			Creatinine	79.6	umol/L	61.9	106.1
			Urea Nitrogen	8.93	mmol/L	7.86	10.36

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Laboratory Results - Hematology							
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**
COVID Illness Visit 1	14OCT2020 (24)	16OCT2020 (26)	Basophils	0	10^9/L	0	0.01
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.44	L/L	0.38	0.49
			Hemoglobin	154	g/L	122	167
			Lymphocytes	1.21	10^9/L	1.1	3.4
			Monocytes	0.48	10^9/L	0.3	1.1
			Neutrophils	2.94	10^9/L	1.5	7.9
			Platelets	160	10^9/L	137	352
			Erythrocytes	5.27	10^12/L	4.4	5.5
			Leukocytes	4.63	10^9/L	4.1	12.2
		18OCT2020 (28)	Basophils	0.01	10^9/L	0	0.3
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.37	L/L	0.38	0.49
			Hemoglobin	129	g/L	122	167
			Lymphocytes	1.58	10^9/L	1.1	3.4
			Monocytes	0.45	10^9/L	0.3	1.1
			Neutrophils	2.39	10^9/L	1.5	7.9
			Platelets	165	10^9/L	137	352
			Erythrocytes	4.34	10^12/L	4.4	5.5
			Leukocytes	4450	10^9/L	4100	12200
		19OCT2020 (29)	Basophils	0	10^9/L	0	0.3
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.37	L/L	0.38	0.49
			Hemoglobin	131	g/L	122	167
			Lymphocytes	2.94	10^9/L	1.5	7.9

Laboratory Results - Hematology							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
			Monocytes	0.48	10^9/L	0.3	1.1
			Neutrophils	12.5	10^9/L	1.5	7.9
			Platelets	160	10^9/L	137	352
			Erythrocytes	4.31	10^12/L	4.4	5.5
			Leukocytes	4.63	10^9/L	4.1	12.2
		20OCT2020 (30)	Basophils	0.02	10^9/L	0	0.5
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	37.1	10^6/cu mm	38.2	49.2
			Hemoglobin	131	g/L	122	167
			Lymphocytes	1.86	10^9/L	1.1	3.4
			Monocytes	0.44	10^9/L	0.3	1.1
			Neutrophils	3.35	10^9/L	1.5	7.9
			Platelets	172	10^9/L	137	352
			Erythrocytes	4.36	10^12/L	4.4	5.5
			Leukocytes	5.8	10^9/L	4.1	12.2

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Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	14OCT2020 (24)	16OCT2020 (26)	1					80 %
		18OCT2020 (28)	2	130 mmHg	72 mmHg		47 beats/min	
		19OCT2020 (29)	3					95 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging								
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment
1	COVID Illness Visit 1	14OCT2020 (24)	16OCT2020	CHEST		CT SCAN	NA	ABNORMAL

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Imaging	
Assessment Number	**If Abnormal, Specify Findings**
1	Lungs: Multifocal ground glass opacities scattered throughout the lungs bilaterally. No Pleura effusions. Extensive coronary atherosclerotic classifications. Normal thickness of the Pericardium.

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	21SEP2020	
Withdrawn	VACCINATION	12OCT2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1047 10471252, a 63-year-old white male with a height of 185.42 cm, a weight of 111.36 kg, and a BMI of 32.3 kg/m2, received Dose 1 on 21 Sep 2020. The subject had a reported medical history of ankle fracture, arthrodesis, cholecystectomy, cholelithiasis, rotator cuff repair, and rotator cuff syndrome (all in 2010); type 2 diabetes mellitus (since 2010); atrial fibrillation (since 2012); knee arthroplasty (in 2015); and drug hypersensitivity (ACE inhibitor allergy, since 2015). The central laboratory SARS-CoV-2 NAAT result was negative at Visit 1. The central laboratory N-binding antibody result was negative at Visit 1. On 14 Oct 2020 (Day 24), the subject was diagnosed with severe COVID-19 and reported diarrhea, fever, headache, new or increased cough, new or increased muscle pain, and new or increased shortness of breath, with the first symptom starting on 12 Oct 2020, 21 days after receiving Dose 1, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 14 Oct 2020 (Day 24) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 14 Oct 2020 (Day 24) was positive. The subject went to the emergency room (once), went to his primary care physician (once), and visited a COVID test center/regional hospital (once). The subject was hospitalized on 16 Oct 2020 (Day 26) and remained hospitalized as of the last available report. On 16 Oct 2020 (Day 26), the subject had an oxygen saturation of 80% and required high-flow oxygen therapy. On 18 Oct 2020 (Day 28), the subject had a heart rate of 47 beats per minute and blood pressure of 130/72 mmHg. On 19 Oct 2020 (Day 29), the subject had an oxygen saturation of 95%. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, oxygen saturation ⩽93%, and requirement for high-flow oxygen therapy). On 16 Oct 2020 (Day 26), the creatinine was 114.9 µmol/L (normal range [NR]: 61.9 - 106.1 µmol/L) and blood urea nitrogen (BUN) was 10 mmol/L (NR: 2.86 - 8.21 mmol/L). On 17 Oct 2020 (Day 27), alanine aminotransferase (ALT) was 0.5001 µkat/L (NR: <0.65013 µkat/L), aspartate aminotransferase (AST) was 0.86684 µkat/L (NR: <0.70014 µkat/L), bilirubin was 6.8 µmol/L (NR: <17.1 µmol/L), BUN was 10.71 mmol/L (NR: 2.86 - 8.21 mmol/L), creatinine was 114.9 µmol/L (NR: 61.9 - 106.1 µmol/L), and C-reactive protein was 1.1 mg/L (NR: <0.5 mg/L). On 18 Oct 2020 (Day 28), the ALT was 0.63346 µkat/L (NR: <0.65013 µkat/L), AST was 0.3334 µkat/L (NR: <0.70014 µkat/L), bilirubin was 5.1 µmol/L (NR: <17.1 µmol/L), and BUN was 8.57 mmol/L (NR: 2.86 - 8.21 mmol/L). On 19 Oct 2020 (Day 29), the ALT was 0.51677 µkat/L (NR: <0.65013 µkat/L), AST was 0.28339 µkat/L (NR: <0.70014 µkat/L), bilirubin was 5.1 µmol/L (NR: <17.1 µmol/L), and BUN was 10.36 mmol/L (NR: 1.79 - 10 mmol/L). On 16 Oct 2020 (Day 26), a computed tomographic scan of the chest showed multifocal ground glass opacities scattered throughout the lungs bilaterally. No pleural effusions were observed. Extensive coronary atherosclerotic calcifications with normal thickness of the pericardium were observed. The subject was discontinued from the study intervention on 14 Oct 2020 since he no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1958	61	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.79 cm	115.05 kg	33.6 kg/m2	18SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Bilateral Eye Radial Keratotomy	Keratotomy	1981	Past
Prostate Cancer	Prostate cancer	2005	Past
Prostatectomy	Prostatectomy	2005	Past
ERECTILE DYSFUNCTION	Erectile dysfunction	2010	Present
Hypertension	Hypertension	2015	Present
Asymptomatic Tachycardia	Tachycardia	18SEP2020	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	18SEP2020 (1)	17:37

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	18SEP2020 (1)	18SEP2020 (1)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	18SEP2020 (1)	18SEP2020 (1)	SERUM	NEGATIVE
Visit 2	08OCT2020 (21)	08OCT2020 (21)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 28SEP2020 (11)/ 25SEP2020 (8)/ 06OCT2020 (19)	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	

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Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 2 / 27OCT2020 (40)/ 25OCT2020 (38)/ ONGOING	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	NO		Pain
	NO		Primary cough headache

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	28SEP2020 (11)	Covid-19	26SEP2020 (9)	3	COVID-19

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SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	28SEP2020 (11)	28SEP2020 (11)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 2	27OCT2020 (40)	27OCT2020 (40)	NASAL_SWAB	NEGATIVE

SARS-COV-2 Test - Local Laboratory						
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**	**Test Result**
1	COVID Illness Visit 1	28SEP2020 (11)	26SEP2020 (9)	SWABBED MATERIAL	NASOPHARYNX	POSITIVE

SARS-COV-2 Test - Local Laboratory			
Lab Test Number	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	The trade name of swab was not in the medical report. CRC called and was given name below.	OTHER	NALT Unknown

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Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	28SEP2020 (11)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	YES	1	NA
COVID Illness Visit 2	27OCT2020 (40)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

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Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	28SEP2020 (11)	28SEP2020 (11)	1	118 mmHg	84 mmHg	28 breaths/min	137 beats/min	96 %
COVID Illness Visit 2	27OCT2020 (40)	27OCT2020 (40)	2	125 mmHg	91 mmHg	22 breaths/min	108 beats/min	98 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	18SEP2020	
Withdrawn	VACCINATION	28SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1116 11161253, a 61-year-old white male with a height of 184.79 cm, a weight of 115.05 kg, and a BMI of 33.6 kg/m2, received Dose 1 on 18 Sep 2020. The subject had a reported medical history of keratotomy (in 1981), prostate cancer and prostatectomy (both in 2005), erectile dysfunction (since 2010), hypertension (since 2015), and tachycardia (since 18 Sep 2020). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 (18 Sep 2020 [Day 1]) and positive at Visit 2 (08 Oct 2020 [Day 21]). The central laboratory N-binding antibody result was negative at Visit 1 (18 Sep 2020 [Day 1]). On 26 Sep 2020 (Day 9), the subject was diagnosed with severe COVID-19 and reported chills, fever, new or increased cough, and new or increased muscle pain, with the first symptom starting on 25 Sep 2020, 7 days after receiving Dose 1 and the last symptom resolved on 06 Oct 2020 (Day 19). The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 26 Sep 2020 (Day 9) was positive. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 28 Sep 2020 (Day 11) was positive. On 28 Sep 2020 (Day 11), the subject had a heart rate of 137 beats per minute (bpm), blood pressure of 118/84 mmHg, respiratory rate of 28 breaths per minute, and oxygen saturation of 96% on room air. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and heart rate more than 125 bpm). The subject had an urgent care visit (once). The subject was discontinued from the study intervention on 28 Sep 2020 since he no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1957	63	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.5 cm	87.05 kg	31 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
hypertension	Hypertension	2002	Present
mild anxiety depression	Depression	2010	Present
chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2018	Present
fatty liver	Hepatic steatosis	2018	Present
Diabetes Mellitus Type 2	Type 2 diabetes mellitus	25FEB2020	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	27AUG2020 (1)	11:52

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	27AUG2020 (1)	27AUG2020 (1)	NASAL_SWAB	NEGATIVE

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SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	27AUG2020 (1)	27AUG2020 (1)	SERUM	NEGATIVE
Visit 2	09OCT2020 (44)	09OCT2020 (44)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	Yes

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Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 02SEP2020 (7)/ 01SEP2020 (6)/ ONGOING	YES	CHILLS	
	YES	DIARRHEA	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	02SEP2020 (7)	COVID-19 PNEUMONIA	05SEP2020 (10)	4	COVID-19 pneumonia

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SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	02SEP2020 (7)	03SEP2020 (8)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	02SEP2020 (7)	03SEP2020 (8)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	02SEP2020 (7)	08SEP2020 (13)	SWABBED MATERIAL	NASOPHARYNX
3	COVID Illness Visit 1	02SEP2020 (7)	09SEP2020 (14)	SWABBED MATERIAL	NASOPHARYNX
4	COVID Illness Visit 1	02SEP2020 (7)	14SEP2020 (19)	SWABBED MATERIAL	NASOPHARYNX
5	COVID Illness Visit 1	02SEP2020 (7)	15SEP2020 (20)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		LABCORP COVID-19 RT-PCR TEST	
2	POSITIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	
3	POSITIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	

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SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
4	POSITIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	
5	NEGATIVE		THERMOFISHER APPL BIO TAQPATH COVID-19 COMBO KIT	

Health Care Utilization					
Visit	**Visit Date (Study Day)**	**Physician, Healthcare Professional, or Other Type of Practitioner (Specify)**	**Occurrence of Visits/Contacts**	**Number of Visits or Contacts**	**Other Type of Practitioner (Specify)**
COVID Illness Visit 1	02SEP2020 (7)	OTHER	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		SPECIALIST	YES	1	NA
		EMERGENCY ROOM	YES	1	NA
		PRIMARY CARE PHYSICIAN	YES	5	NA

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Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	02SEP2020 (7)	HOSPITALIZATION STATUS	HOSPITAL	05SEP2020 (10)	19SEP2020 (24)
COVID Illness Visit 1	02SEP2020 (7)	HOSPITALIZATION STATUS	ICU	05SEP2020 (10)	19SEP2020 (24)

Respiratory Treatment

Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	02SEP2020 (7)	1	YES	HIGH FLOW OXYGEN THERAPY	05SEP2020 (10)	09SEP2020 (14)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Visit	Visit Date (Study Day)	Subcategory of Clinical Event	Respiratory Illness Diagnosis	Date of Diagnosis: (Study Day)	End Date or Ongoing	Toxicity Grade	MedDRA Preferred Term
COVID Illness Visit 1	02SEP2020 (7)	SIGNIFICANT ACUTE HEPATIC DYSFUNCTION	ACUTE LIVER DYSFUNCTION	03SEP2020 (8)	09SEP2020 (14)	2	Hepatic function abnormal
COVID Illness Visit 1	02SEP2020 (7)	SIGNIFICANT ACUTE RENAL DYSFUNCTION	ACUTE RENAL AZOTEMIA	03SEP2020 (8)	ONGOING	2	Azotaemia

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Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	02SEP2020 (7)	03SEP2020 (8)	Alkaline Phosphatase	1.2	ukat/L	0.65	1.95
			Alanine Aminotransferase	2.85057	ukat/L	0	0.73348
			Aspartate Aminotransferase	3.21731	ukat/L	0	0.6668
			Bilirubin	10.3	umol/L	0	20.5
			Creatinine	139.7	umol/L	67.2	112.3
			Urea Nitrogen	10.71	mmol/L	2.86	9.64
		05SEP2020 (10)	Alkaline Phosphatase	1.48	ukat/L	0.77	1.93
			Alanine Aminotransferase	2.60052	ukat/L	0.23338	1.05021
			Aspartate Aminotransferase	2.55051	ukat/L	0.25005	0.61679
			Bilirubin	5.1	umol/L	6.8	13.7
			Creatinine	123.8	umol/L	53	114.9
			C Reactive Protein	8	mg/L	0	9
			Urea Nitrogen	11.43	mmol/L	2.5	6.43

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	02SEP2020 (7)	05SEP2020 (10)	Basophils	0.3	%	0	3
			Eosinophils	0.1	%	0	6
			Hematocrit	0.46	L/L	0.42	0.52
			Hemoglobin	154	g/L	140	180
			Lymphocytes	14.7	%	18	46
			Monocytes	9	%	0	11
			Neutrophils	75.9	%	47	75
			Platelets	186	10^9/L	130	400
			Erythrocytes	5.14	10^12/L	4.7	6.1
			Leukocytes	6.3	10^9/L	4.8	10.8

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	02SEP2020 (7)	05SEP2020 (10)	1					88 %
		14SEP2020 (19)	2					84 %
		29SEP2020 (34)	3					89 %
		01OCT2020 (36)	4					92 %

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Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging								
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment
1	COVID Illness Visit 1	02SEP2020 (7)	05SEP2020	CHEST		X-RAY	NA	ABNORMAL
2	COVID Illness Visit 1	02SEP2020 (7)	08SEP2020	CHEST		X-RAY	NA	ABNORMAL
3	COVID Illness Visit 1	02SEP2020 (7)	12SEP2020	CHEST		X-RAY	NA	ABNORMAL
4	COVID Illness Visit 1	02SEP2020 (7)	14SEP2020	CHEST		X-RAY	NA	ABNORMAL
5	COVID Illness Visit 1	02SEP2020 (7)	30SEP2020	CHEST		X-RAY	NA	ABNORMAL

Imaging	
Assessment Number	If Abnormal, Specify Findings
1	Bibasilar diffuse mixed infiltrates. No focal infiltrates, effusions or pneumothoraces. Mild overinflation, chronic appearing diffuse interstitial prominence.
2	Bibasilar mixed infiltrates, greater to the LEFT. Mild overinflation mild, chronic appearing diffuse interstitial prominence.
3	Scattered alveolar interstitial changes are seen in the perihilar region and at the lung bases. Findings are consistent with atypical infiltrates.

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Imaging	
Assessment Number	**If Abnormal, Specify Findings**
4	There are bilateral interstitial infiltrates within both lungs. Interval improvement is observed. No alveolar consolidation or pleural effusion is noted. No acute osseous abnormality is detected.
5	Chronic interstitial fibrosis in lungs, especially on right side with suggestion of patchy infiltrates in both lower lobes, especially on the left side. No evidence of pleural effusions.

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27AUG2020	
Withdrawn	VACCINATION	08SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1156 11561044, a 63-year-old white male with a height of 167.5 cm, a weight of 87.05 kg, and a BMI of 31 kg/m2, received Dose 1 on 27 Aug 2020.
The subject had a reported medical history of hypertension (since 2002), depression (since 2010), chronic obstructive pulmonary disease and hepatic steatosis (both since 2018), and type 2 diabetes mellitus (since 25 Feb 2020).
The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1.
On 05 Sep 2020 (Day 10), the subject was diagnosed with severe COVID-19 pneumonia and reported chills, diarrhea, fever, new or increased cough, new or increased muscle pain, new or increased shortness of breath, and new or increased sore throat, with the first symptom starting on 01 Sep 2020, 5 days after receiving Dose 1, and at least 1 symptom ongoing as of the last available report.
The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Sep 2020 (Day 8) was positive.
The local laboratory SARS-CoV-2 NAAT result(s) at the time of the COVID-19 illness on 03 Sep 2020 (Day 8), 08 Sep 2020 (Day 13), 09 Sep 2020 (Day 14), and 14 Sep 2020 (Day 19) were positive and on 15 Sep 2020 (Day 20) was negative.
The subject went to his primary care physician (5 times), to the emergency room (once), and to a specialist (once).
The subject was hospitalized and was in the intensive care unit on 05 Sep 2020 (Day 10) for 15 days and discharged on 19 Sep 2020 (Day 24).
The subject experienced significant acute renal dysfunction (moderate azotemia) and significant acute hepatic dysfunction (moderate) on 03 Sep 2020 (Day 8).
On 03 Sep 2020 (Day 8), the alanine aminotransferase (ALT) was 2.85057 µkat/L (normal range [NR]: 0 - 0.73348 µkat/L), aspartate aminotransferase (AST) was 3.21731 µkat/L (NR: 0 - 0.6668 µkat/L), creatinine was 139.7 µmol/L (NR: 67.2 - 112.3 µmol/L), and blood urea nitrogen (BUN) was 10.71 mmol/L (NR: 2.86 – 9.64 mmol/L).
On 05 Sep 2020 (Day 10), the ALT was 2.60052 µkat/L (NR: 0.23338 - 1.05021 µkat/L), AST was 2.55051 µkat/L (NR: 0.25005 - 0.61679 µkat/L), bilirubin was 5.1 µmol/L (NR: 6.8 – 13.7 µmol/L), creatinine was 123.8 µmol/L (NR: 53 - 114.9 µmol/L), BUN was 11.43 mmol/L (NR: 2.5 – 6.43 mmol/L), lymphocytes were 14.7% (NR: 18% - 46%), and neutrophils were 75.9% (NR: 47% - 75%).
The subject had an oxygen saturation of 88% on 05 Sep 2020 (Day 10), 84% on 14 Sep 2020 (Day 19), 89% on room air on 29 Sep 2020 (Day 34), and 92% on room air on 01 Oct 2020 (Day 36).
The subject required high-flow oxygen therapy from 05 Sep 2020 (Day 10) to 09 Sep 2020 (Day 14).
The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, admission to an intensive care unit, significant acute renal dysfunction, significant acute hepatic dysfunction, oxygen saturation of ⩽93%, and requirement for high-flow oxygen therapy).
Chest radiographs revealed: bibasilar diffuse mixed infiltrates, no focal infiltrates, effusions or pneumothoraxes, mild overinflation, chronic appearing diffuse interstitial prominence on 05 Sep 2020 (Day 10); bibasilar mixed infiltrates, greater to the left, mild overinflation, chronic appearing diffuse interstitial prominence on 08 Sep 2020 (Day 13); scattered alveolar interstitial changes were observed in the perihilar region and at the lung bases, findings were consistent with atypical infiltrates on 12 Sep 2020 (Day 17); bilateral interstitial infiltrates within both lungs, interval improvement was observed, no alveolar consolidation or pleural effusion was noted, and no acute osseous abnormality was detected on 14 Sep 2020 (Day 19), and chronic interstitial fibrosis on right side of the lungs, with patchy infiltrates in both lower lobes, especially on the left side; and no evidence of pleural effusions were observed on 30 Sep 2020 (Day 35).
The subject was discontinued from the study intervention on 08 Sep 2020 since he no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1977	43	American Indian or Alaska Native	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
185.42 cm	139.73 kg	40.6 kg/m2	13OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Diabetes Type 2	Type 2 diabetes mellitus	2000	Present
Kidney Stones	Nephrolithiasis	2004	Past
BPH	Benign prostatic hyperplasia	2019	Present
Congesutive Heart Failure	Cardiac failure congestive	JUL2019	Present
Coronary Stent placement	Coronary arterial stent insertion	JUL2019	Past
Circumcision	Circumcision	OCT2019	Past
Coronary Artery Disease	Coronary artery disease	15JUL2020	Present

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Hypercholesterolemia	Hypercholesterolaemia	15JUL2020	Present
Hypertension	Hypertension	15JUL2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	13OCT2020 (1)	11:44
2	Placebo	02NOV2020 (21)	09:52

Adverse Events
No Adverse Events

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
Dexamethasone (Decadron)	DEXAMETHASONE	03NOV2020	06NOV2020	INTRAVENOUS
Remdesivir	REMDESIVIR	03NOV2020	03NOV2020	INTRAVENOUS
Remdesivir	REMDESIVIR	04NOV2020	06NOV2020	INTRAVENOUS
Dexamethasone	DEXAMETHASONE	07NOV2020	ONGOING	ORAL

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Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	13OCT2020 (1)	13OCT2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	13OCT2020 (1)	13OCT2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 03NOV2020 (22)/ 01NOV2020 (20)/ ONGOING	YES	CHILLS	
	YES	VOMITING	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	03NOV2020 (22)	Viral Pneumonia secondary to COVID-19	03NOV2020 (22)	3	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory
No SARS-COV-2 Test - Central Laboratory

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SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	03NOV2020 (22)	03NOV2020 (22)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	03NOV2020 (22)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	1	NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	03NOV2020 (22)	HOSPITALIZATION STATUS	HOSPITAL	03NOV2020 (22)	06NOV2020 (25)

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

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Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	03NOV2020 (22)	03NOV2020 (22)	Alkaline Phosphatase	2.33	ukat/L	0.63	2.1
			Alanine Aminotransferase	0.8335	ukat/L	0	0.8335
			Aspartate Aminotransferase	0.90018	ukat/L	0.28339	0.98353
			Bilirubin	8.6	umol/L	3.4	22.2
			Creatinine	53	umol/L	61.9	114.9
			C Reactive Protein	<5	mg/L	0	5
			Urea Nitrogen	3.93	mmol/L	3.21	7.14

Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	03NOV2020 (22)	03NOV2020 (22)	Basophils	0	10^9/L	0	500
			Eosinophils	0	10^9/L	0	1000
			Hematocrit	0.48	L/L	0.41	0.49
			Hemoglobin	161	g/L	140	180
			Lymphocytes	800	10^9/L	900	4400
			Monocytes	1000	10^9/L	0	1000
			Neutrophils	3800	10^9/L	1500	8000
			Platelets	198000	10^9/L	180000	430000
			Erythrocytes	5.41	10^12/L	4	5.6
			Leukocytes	5700	10^9/L	4500	11000

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Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	03NOV2020 (22)	03NOV2020 (22)	1	153 mmHg	97 mmHg	32 breaths/min	72 beats/min	95 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

Imaging

Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment
1	COVID Illness Visit 1	03NOV2020 (22)	03NOV2020	CHEST		CT SCAN	NA	ABNORMAL
2	COVID Illness Visit 1	03NOV2020 (22)	03NOV2020	CHEST		X-RAY	NA	NORMAL

Imaging	
Assessment Number	**If Abnormal, Specify Findings**
1	Small patchy density in R Upper lobe, likely inflammatory/infectious with minor bibasilar subsegmental ateletasis; R coronary atherosclerosis vs. stent
2	

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	13OCT2020	
	VACCINATION		
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1221 12211002, a 43-year-old American Indian or Alaska Native male with a height of 185.42 cm, a weight of 139.73 kg, and a BMI of 40.6 kg/m2, received Dose 1 on 13 Oct 2020 and Dose 2 on 02 Nov 2020 (Day 21). The subject had a reported medical history of type 2 diabetes mellitus (since 2000); nephrolithiasis (in 2004); benign prostatic hyperplasia (since 2019); congestive cardiac failure (since Jul 2019); coronary arterial stent insertion (in Jul 2019); circumcision (in Oct 2019); and coronary artery disease, hypercholesterolemia, and hypertension (all since 15 Jul 2020). The central laboratory SARS-CoV-2 NAAT result(s) was negative at Visit 1 and positive at Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 03 Nov 2020 (Day 22), the subject was diagnosed with severe COVID-19 pneumonia and reported chills and vomiting, with the first symptom starting on 01 Nov 2020, 19 days after receiving Dose 1, and at least 1 symptom ongoing as of the last available report. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 03 Nov 2020 (Day 22) was positive. The subject went to the emergency room (ER) (once). On 01 Nov 2020 (Day 20), the subject developed mild nasal congestion, which was reported to be resolved on 02 Nov 2020 (Day 21). However, during Visit 2, the subject denied having any symptoms when queried if he had been ill in the previous 2 days. The subject received Dose 2 on 02 Nov 2020 (Day 21), and he developed nausea and vomiting around noon and developed chills later in the evening. On 03 Nov 2020 (Day 22), the subject went to the ER for further evaluation, at which time, he was noted to have nausea, vomiting, loss of appetite, difficulty breathing, sore throat, muscle aches, and chest tightness. The subject's body temperature was 97.2 F°. The ER nurse noted that "breath sounds were within normal limits" (respiratory rate: 19 breaths per minute). The subject was treated with ondansetron 4 mg for nausea. On 03 Nov 2020 (Day 22), the subject had a heart rate of 72 beats per minute, blood pressure of 153/97 mmHg, respiratory rate of 32 breaths per minute, and oxygen saturation of 95%. A respiratory examination showed mild respiratory distress with tachypnea. The subject received dexamethasone (intravenous [IV] from 03 Nov 2020 to 06 Nov 2020 and oral from 07 Nov 2020) and remdesivir (IV from 03 Nov 2020 to 06 Nov 2020) at the time of the COVID-19 illness. The influenza A and B virus tests were negative. The subject was hospitalized on 03 Nov 2020 (Day 22) for 4 days and discharged on 06 Nov 2020 (Day 25). A chest radiograph on 03 Nov 2020 (Day 22) was normal. Computed tomographic pulmonary angiography of the chest on 03 Nov 2020 (Day 22) was abnormal with small patchy density in the right upper lobe, likely inflammatory/infectious with minor bibasilar subsegmental atelectasis; right coronary atherosclerosis vs. stent. On 03 Nov 2020 (Day 22), the subject's glucose was 312 mg/dL (normal range [NR]: 74 – 106 mg/dL), white blood cell count was 5.7 × 103/mm3 (NR: 4.5 – 11.0 × 103/mm3), alkaline phosphatase was 2.33 µkat/L (NR: 0.63 – 2.1 µkat/L), and lymphocyte count was 800 × 109/L (NR: 900 – 4400 × 109/L). The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, mild respiratory distress [respiratory rate >30 breaths per minute] with tachypnea).

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1979	41	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160.9 cm	71.3 kg	27.5 kg/m2	07SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
headache	Headache	2010	Present
Albright's osteodystrophy	Congenital osteodystrophy	2017	Present

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	07SEP2020 (1)	13:18
2	BNT162b2	02OCT2020 (26)	13:50

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Fatigue	fatigue	07SEP2020 (1)	20:00	10SEP2020 (4)		4	1
2	MUSC	Myalgia	myalgia	07SEP2020 (1)	20:00	10SEP2020 (4)		4	1
3	EYE	Ulcerative keratitis	corneal ulcer right eye	20SEP2020 (14)		27SEP2020 (21)		8	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (10SEP2020)	Study Treatment	1	1	N
2	TC	N	Resolved (10SEP2020)	Study Treatment	1	1	N
3	TC	N	Resolved (27SEP2020)	NOT RELATED/OTHER: prolonged use of contact lens	1	14	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	07SEP2020 (1)	07SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	07SEP2020 (1)	07SEP2020 (1)	SERUM	NEGATIVE
Visit 2	02OCT2020 (26)	02OCT2020 (26)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 07NOV2020 (62)/ 06NOV2020 (61)/ ONGOING	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Rhinitis

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	07NOV2020 (62)	COVID-19	07NOV2020 (62)	2	COVID-19

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SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	07NOV2020 (62)	07NOV2020 (62)	NASAL_SWAB	POSITIVE
2	COVID Illness Visit 1	07NOV2020 (62)	11NOV2020 (66)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	07NOV2020 (62)	07NOV2020 (62)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	NALT Unknown

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Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	07NOV2020 (62)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

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Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	07NOV2020 (62)	07NOV2020 (62)	1	133 mmHg	92 mmHg	16 breaths/min	89 beats/min	93 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07SEP2020	
Completed	VACCINATION	03NOV2020	
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1226 12261599, a 41-year-old white female with a height of 160.9 cm, a weight of 71.3 kg, and a BMI of 27.5 kg/m2, received Dose 1 on 07 Sep 2020 and Dose 2 on 02 Oct 2020 (Day 26). The subject had a reported medical history of headache (since 2010) and congenital osteodystrophy (since 2017). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 07 Nov 2020 (Day 62), the subject was diagnosed with severe COVID-19 and reported new loss of taste or smell, new or increased cough, new or increased sore throat, and rhinitis, with the first symptom starting on 06 Nov 2020, 35 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on 07 Nov 2020 (Day 62) and on 11 Nov 2020 (Day 66) were positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 07 Nov 2020 (Day 62) was positive. The subject did not have any contact with nonstudy healthcare personnel. On 07 Nov 2020 (Day 62), the subject had a heart rate of 89 beats per minute, blood pressure of 133/92 mm Hg, respiratory rate of 16 breaths per minute, and oxygen saturation of 93% on room air. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ≤93%).

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1968	52	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
184.3 cm	91.1 kg	26.8 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Vasectomy	Vasectomy	2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	08SEP2020 (1)	11:46
2	Placebo	30SEP2020 (23)	13:30

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Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	08SEP2020 (1)	08SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	08SEP2020 (1)	08SEP2020 (1)	SERUM	NEGATIVE
Visit 2	30SEP2020 (23)	30SEP2020 (23)	NASAL_SWAB	NEGATIVE

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Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 05NOV2020 (59)/ 02NOV2020 (56)/ ONGOING	YES	CHILLS	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Rhinorrhoea

Diagnosis of Potential COVID-19 Illness
No Diagnosis of Potential COVID-19 Illness

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	05NOV2020 (59)	05NOV2020 (59)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory
No SARS-COV-2 Test - Local Laboratory

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Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	05NOV2020 (59)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

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Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	05NOV2020 (59)	05NOV2020 (59)	1	132 mmHg	78 mmHg	16 breaths/min	83 beats/min	92 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	29OCT2020	
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1226 12261624, a 52-year-old white male with a height of 184.3 cm, a weight of 91.1 kg, and a BMI of 26.8 kg/m2, received Dose 1 on 08 Sep 2020 and Dose 2 on 30 Sep 2020 (Day 23). The subject had a reported medical history of vasectomy (since 2010). The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject reported chills, new or increased cough, new or increased muscle pain, new or increased sore throat, and rhinorrhea, with the first symptom starting on 02 Nov 2020, 33 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 05 Nov 2020 (Day 59) was positive. No local laboratory SARS-CoV-2 NAAT was done. The subject did not have any contact with nonstudy healthcare personnel. On 05 Nov 2020 (Day 59), the subject had a heart rate of 83 beats per minute, blood pressure of 132/78 mm Hg, respiratory rate of 16 breaths per minute, and oxygen saturation of 92% on room air. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ⩽93%).

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
171 cm	103 kg	35.2 kg/m2	21AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	21AUG2020 (1)	16:00
2	Placebo	14SEP2020 (25)	11:00

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Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	CARD	Atrioventricular block second degree	Second degree AV block (Mobitz II)	10NOV2020 (82)	10:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	N	Y	Yes	NOT RELATED/OTHER: unknown	2	58	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	21AUG2020 (1)	21AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	21AUG2020 (1)	21AUG2020 (1)	SERUM	NEGATIVE
Visit 2	14SEP2020 (25)	14SEP2020 (25)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 2	Yes	Yes

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Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 25AUG2020 (5)/ 24AUG2020 (4)/ 16SEP2020 (27)	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	
	NO		Rhinorrhoea
COVID Illness Visit 2 / 29OCT2020 (70)/ 26OCT2020 (67)/ ONGOING	YES	FEVER	
	NO		Fatigue
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

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Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 2	29OCT2020 (70)	COVID-19 pharyngitis.	29OCT2020 (70)	2	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	25AUG2020 (5)	25AUG2020 (5)	NASAL_SWAB	NEGATIVE
2	COVID Illness Visit 2	29OCT2020 (70)	29OCT2020 (70)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	25AUG2020 (5)	25AUG2020 (5)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	25AUG2020 (5)	10SEP2020 (21)	SWABBED MATERIAL	NASOPHARYNX
3	COVID Illness Visit 2	29OCT2020 (70)	29OCT2020 (70)	SWABBED MATERIAL	NASOPHARYNX

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SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
3	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	25AUG2020 (5)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	29OCT2020 (70)	OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
		EMERGENCY ROOM	YES	3	NA

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Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 2	29OCT2020 (70)	HOSPITALIZATION STATUS	HOSPITAL	06NOV2020 (78)	14NOV2020 (86)

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry

No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology

No Laboratory Results - Hematology

Vital Signs - COVID-19

Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 2	29OCT2020 (70)	06NOV2020 (78)	1					92 %

Oxygenation Parameters

No Oxygenation Parameters

Concomitant Medications - Vasopressors

No Concomitant Medications - Vasopressors

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FDA-CBER-2021-5683-1788398

Imaging									
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	COVID Illness Visit 2	29OCT2020 (70)	02NOV2020	CHEST		X-RAY	NA	ABNORMAL	Right lung base abnormal.

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	16OCT2020	
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1231 12312914, a 50-year-old white male with a height of 171 cm, a weight of 103 kg, and a BMI of 35.2 kg/m2, received Dose 1 on 21 Aug 2020 and Dose 2 on 14 Sep 2020 (Day 25). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 29 Oct 2020 (Day 70), the subject was diagnosed with severe COVID-19 and reported fever, fatigue, headache, new or increased cough, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 26 Oct 2020, 42 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 70) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 70) was positive. On 02 Nov 2020 (Day 74), a chest radiograph revealed right lung base abnormal. On 06 Nov 2020 (Day 78), the subject was admitted to the hospital for COVID-19 pneumonia, with the symptoms of bradycardia and 2 episodes of second grade atrioventricular (AV) block (Mobitz II). On 06 Nov 2020 (Day 78), the subject had an oxygen saturation of 92%. The subject was transferred to a coronary unit on 10 Nov 2020 (Day 82). An electrocardiogram (ECG) showed sinus rhythm without ST elevation; second grade AV block (Mobitz II). On the same day (Day 82), the subject was diagnosed with a serious adverse event of atrioventricular block second degree, resulting in prolonged hospitalization. On 11 Nov 2020 (Day 83), the subject's troponin (unknown subtype) was reported to be normal at 4.5 ng/L and 2.6 ng/L on 13 Nov 2020 (Day 85) (normal ranges not reported). On 12 Nov 2020 (Day 84), an ECG showed sinus rhythm without blockages and echocardiogram was normal. On 13 Nov 2020 (Day 85), an ECG was normal with a cardiac frequency of 76 beats per minute, normal sinus rhythm and no electrical disturbances. The subject remained stable without oxygen requirement and did not receive any treatment for this transitory episode. A 24-hour Holter in 3 channels was scheduled. On 14 Nov 2020 (Day 86), the subject was discharged from the hospital. The atrioventricular block second degree was ongoing as of the last available report. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and oxygen saturation ≤93%).

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1986	34	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172 cm	88 kg	29.7 kg/m2	23AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	23AUG2020 (1)	12:15
2	Placebo	15SEP2020 (24)	19:05

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Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	23AUG2020 (1)	23AUG2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	23AUG2020 (1)	23AUG2020 (1)	SERUM	NEGATIVE
Visit 2	15SEP2020 (24)	15SEP2020 (24)	NASAL_SWAB	NEGATIVE

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Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	Yes

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 29OCT2020 (68)/ 28OCT2020 (67)/ ONGOING	NO		Asthenia
	YES	DIARRHEA	
	YES	FEVER	
	NO		Headache
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	29OCT2020 (68)	COVID-19 and Bilateral pneumonia	02NOV2020 (72)	4	COVID-19 pneumonia

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	29OCT2020 (68)	29OCT2020 (68)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	29OCT2020 (68)	29OCT2020 (68)	SWABBED MATERIAL	NASOPHARYNX
2	COVID Illness Visit 1	29OCT2020 (68)	01NOV2020 (71)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	NEGATIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	
2	POSITIVE	swab performed at the san camilo clinic	OTHER	NALT unknown

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Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	29OCT2020 (68)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details

Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	29OCT2020 (68)	HOSPITALIZATION STATUS	HOSPITAL	01NOV2020 (71)	ONGOING
COVID Illness Visit 1	29OCT2020 (68)	HOSPITALIZATION STATUS	ICU	06NOV2020 (76)	ONGOING

Respiratory Treatment						
Visit	Visit Date (Study Day)	Treatment Identifier	Prespecified Concomitant Nondrug Treatment	Treatment	Start Date (Study Day)	End Date or Ongoing (Study Day)
COVID Illness Visit 1	29OCT2020 (68)	1	YES	MECHANICAL VENTILATION	06NOV2020 (76)	12NOV2020 (82)

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

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Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	29OCT2020 (68)	06NOV2020 (76)	Alkaline Phosphatase	1.12	ukat/L	0.63	2.1
			Alanine Aminotransferase	1.76702	ukat/L	0.25005	0.75015
			Aspartate Aminotransferase	0.8335	ukat/L	0.08335	0.6668
			Bilirubin	12	umol/L	3.4	20.5
			Creatinine	70.7	umol/L	53	110.5
			C Reactive Protein	149.89	mg/L	0.1	10
			Urea Nitrogen	12.14	mmol/L	5	16.07
		07NOV2020 (77)	Alkaline Phosphatase	0.95	ukat/L	0.63	2.1
			Alanine Aminotransferase	1.26692	ukat/L	0.25005	0.75015
			Aspartate Aminotransferase	0.5001	ukat/L	0.08335	0.6668
			Bilirubin	10.3	umol/L	3.4	20.5
			Creatinine	70.7	umol/L	53	110.5
			C Reactive Protein	149.89	mg/L	0.1	10
			Urea Nitrogen	14.28	mmol/L	5	16.07
		10NOV2020 (80)	Alkaline Phosphatase	1.15	ukat/L	0.63	2.1
			Alanine Aminotransferase	3.95079	ukat/L	0.25005	0.75015
			Aspartate Aminotransferase	1.56698	ukat/L	0.08335	0.6668
			Bilirubin	0.5	umol/L	0.3	2.1
			Creatinine	53	umol/L	53	106.1
			Urea Nitrogen	46	mg/L	14	45

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Laboratory Results - Hematology

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	29OCT2020 (68)	06NOV2020 (76)	Basophils	0	10^9/L	0	200000
			Eosinophils	0	10^9/L	0	700000
			Hematocrit	0.41	L/L	0.4	0.54
			Hemoglobin	144	g/L	126	161
			Lymphocytes	695000	10^9/L	600000	2600000
			Monocytes	2000	10^9/L	0	900000
			Neutrophils	7246000	10^9/L	1700000	7600000
			Platelets	262	10^9/L	150	400
		07NOV2020 (77)	Basophils	52000	10^9/L	0	200000
			Eosinophils	3000	10^9/L	0	700000
			Hematocrit	0.33	L/L	0.4	0.54
			Hemoglobin	117	g/L	126	161
			Lymphocytes	327000	10^9/L	600000	2600000
			Monocytes	225000	10^9/L	0	900000
			Neutrophils	5265000	10^9/L	1700000	7600000
			Platelets	238	10^9/L	150	400
			Erythrocytes	4.01	10^9/L	4.25	5.9
		10NOV2020 (80)	Basophils	37000	10^9/L	0	200000
			Eosinophils	25000	10^9/L	0	700000
			Hematocrit	0.33	L/L	0.4	0.54
			Hemoglobin	111	g/L	126	161
			Lymphocytes	1012000	10^9/L	600000	2600000
			Monocytes	232000	10^9/L	0	900000
			Neutrophils	3672000	10^9/L	1700000	7600000
			Platelets	306	10^9/L	150	400

Laboratory Results - Hematology							
Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
			Erythrocytes	3.94	10^9/L	4.25	5.9

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters				
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Arterial Blood Gases PaO2 (mmHg)	FiO2 (Fraction of Inhaled Oxygen)
COVID Illness Visit 1	29OCT2020 (68)	07NOV2020 (77)	103	0.5
COVID Illness Visit 1	29OCT2020 (68)	09NOV2020 (79)	390	0.4

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

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Imaging						
Assessment Number	Visit	Visit Date (Study Day)	Date of Assessment	Location of Assessment	If Other, Specify	Type of Imaging Exam
1	COVID Illness Visit 1	29OCT2020 (68)	01NOV2020	CHEST		CT SCAN
2	COVID Illness Visit 1	29OCT2020 (68)	06NOV2020	CHEST		X-RAY
3	COVID Illness Visit 1	29OCT2020 (68)	07NOV2020	CHEST		X-RAY
4	COVID Illness Visit 1	29OCT2020 (68)	10NOV2020	CHEST		X-RAY

Imaging			
Assessment Number	If Other, Specify	Overall Assessment	If Abnormal, Specify Findings
1	NA	ABNORMAL	bilateral peripheral pneumonic infiltrate
2	NA	ABNORMAL	Bilateral cottony infiltrates are observed with effacement of the right phrenic cost sinus
3	NA	ABNORMAL	bilateral cottony infiltrate
4	NA	ABNORMAL	Bilateral pulmonary parenchymal infiltrate with imaging improvement with respect to previous ones

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	23AUG2020	
Completed	VACCINATION	14OCT2020	
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1231 12313422, a 34-year-old white male with a height of 172 cm, a weight of 88 kg, and a BMI of 29.7 kg/m2, received Dose 1 on 23 Aug 2020 and Dose 2 on 15 Sep 2020 (Day 24). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result is pending. On 29 Oct 2020 (Day 68), the subject was diagnosed with severe COVID-19 and reported asthenia, diarrhea, fever, headache, new or increased cough, and new or increased shortness of breath, with the first symptom starting on 28 Oct 2020, 43 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 68) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 29 Oct 2020 (Day 68) was negative and on 01 Nov 2020 (Day 71) was positive. The subject did not have any contact with nonstudy healthcare personnel. The subject was hospitalized on 01 Nov 2020 (Day 71), and he remained hospitalized as of the last available report. On 01 Nov 2020 (Day 71), the subject required noninvasive positive pressure ventilation. The subject therefore had severe COVID-19 per study protocol criteria (ie, confirmed COVID-19 and requirement for non-invasive positive pressure ventilation). On 03 Nov 2020 (Day 73), a computed tomographic scan of the chest showed bilateral peripheral pneumonic infiltrate.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1970	50	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
180.34 cm	109.09 kg	33.5 kg/m2	14SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Asthma	Asthma	2010	Present
Hypertension	Hypertension	2010	Present
Allergic Rhinitis	Rhinitis allergic	2010	Present
Dyslipidemia	Dyslipidaemia	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	14SEP2020 (1)	09:50

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
Visit 1	14SEP2020 (1)	14SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	14SEP2020 (1)	14SEP2020 (1)	SERUM	NEGATIVE

Case Details		
Visit	>7 Days After Dose 2	Severe
COVID Illness Visit 1	No	Yes

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Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 22SEP2020 (9)/ 21SEP2020 (8)/ 25SEP2020 (12)	YES	CHILLS	
	YES	FEVER	
	YES	NEW OR INCREASED COUGH	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SHORTNESS OF BREATH	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	22SEP2020 (9)	COVID-19 ILLNESS	22SEP2020 (9)	2	COVID-19

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SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	22SEP2020 (9)	22SEP2020 (9)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	22SEP2020 (9)	22SEP2020 (9)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		OTHER	LSU EVT Lab- PCR analysis-CLIA-certified lab

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Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	22SEP2020 (9)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details					
Visit	Visit Date (Study Day)	Hospitalization Category	Hospitalization Term	Admission Date (Study Day)	Discharge Date or Ongoing (Study Day)
COVID Illness Visit 1	22SEP2020 (9)	HOSPITALIZATION STATUS	ICU	22SEP2020 (9)	26SEP2020 (13)

Respiratory Treatment
No Respiratory Treatment

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Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

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Laboratory Results - Clinical Chemistry

Visit	Visit Date (Study Day)	Date of Test (Study Day)	Laboratory Test	Result	Units	Lower Limit Range	Upper Limit Range
COVID Illness Visit 1	22SEP2020 (9)	22SEP2020 (9)	Alkaline Phosphatase	1.15	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.61699	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.73348	ukat/L	0.1667	0.6668
			Bilirubin	8.6	umol/L	1.7	17.1
			Creatinine	88.4	umol/L	44.2	123.8
			C Reactive Protein	13.5	mg/L	0	9
			Urea Nitrogen	4.64	mmol/L	2.14	7.14
		23SEP2020 (10)	Alkaline Phosphatase	1.1	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.56698	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.8335	ukat/L	0.1667	0.6668
			Bilirubin	6.8	umol/L	1.7	17.1
			Creatinine	70.7	umol/L	44.2	123.8
			C Reactive Protein	17.7	mg/L	0	9
			Urea Nitrogen	4.29	mmol/L	2.14	7.14
		24SEP2020 (11)	Alkaline Phosphatase	0.97	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.30026	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.6668	ukat/L	0.1667	0.6668
			Bilirubin	6.8	umol/L	1.7	17.1
			Creatinine	68.1	umol/L	44.2	123.8
			C Reactive Protein	0.78	mg/L	0	0.9
			Urea Nitrogen	3.21	mmol/L	2.14	7.14
		25SEP2020 (12)	Alkaline Phosphatase	1.03	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.35027	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.65013	ukat/L	0.1667	0.6668
			Bilirubin	5.1	umol/L	1.7	17.1

Laboratory Results - Clinical Chemistry							
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**
			Creatinine	64.5	umol/L	44.2	123.8
			Urea Nitrogen	4.29	mmol/L	2.14	7.14
		26SEP2020 (13)	Alkaline Phosphatase	1	ukat/L	0.92	2.25
			Alanine Aminotransferase	1.1669	ukat/L	0.1667	0.73348
			Aspartate Aminotransferase	0.46676	ukat/L	0.1667	0.6668
			Bilirubin	5.1	umol/L	1.7	17.1
			Creatinine	70.7	umol/L	44.2	123.8
			Urea Nitrogen	4.29	mmol/L	2.14	7.14

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Laboratory Results - Hematology							
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**
COVID Illness Visit 1	22SEP2020 (9)	23SEP2020 (10)	Basophils	0.03	10^9/L	0	0.2
			Eosinophils	0	10^9/L	0	0.5
			Hematocrit	0.41	L/L	0.37	0.47
			Hemoglobin	138	g/L	125	163
			Lymphocytes	1.4	10^9/L	1	4.8
			Monocytes	1.1	10^9/L	0.3	1
			Neutrophils	2.4	10^9/L	1.8	7.7
			Platelets	224	10^9/L	150	350
			Erythrocytes	4.2	10^12/L	4.6	6.2
			Leukocytes	5.03	10^9/L	3.9	12.7
		24SEP2020 (11)	Basophils	0.02	10^9/L	0	0.2
			Eosinophils	0.1	10^9/L	0	0.5
			Hematocrit	0.39	L/L	0.37	0.47
			Hemoglobin	131	g/L	125	163
			Lymphocytes	1.7	10^9/L	1	4.8
			Monocytes	0.8	10^9/L	0.3	1
			Neutrophils	1.4	10^9/L	1.8	7.7
			Platelets	199	10^9/L	150	350
			Erythrocytes	4.07	10^12/L	4.6	6.2
			Leukocytes	4.01	10^9/L	3.9	12.7
		25SEP2020 (12)	Basophils	0.02	10^9/L	0	0.2
			Eosinophils	0.1	10^9/L	0	0.5
			Hematocrit	0.42	L/L	0.37	0.47
			Hemoglobin	143	g/L	125	163
			Lymphocytes	2.3	10^9/L	1	4.8

Laboratory Results - Hematology							
Visit	**Visit Date (Study Day)**	**Date of Test (Study Day)**	**Laboratory Test**	**Result**	**Units**	**Lower Limit Range**	**Upper Limit Range**
			Monocytes	0.6	10^9/L	0.3	1
			Neutrophils	1.1	10^9/L	1.8	7.7
			Platelets	217	10^9/L	150	350
			Erythrocytes	4.4	10^12/L	4.6	6.2
			Leukocytes	4.11	10^9/L	3.9	12.7
		26SEP2020 (13)	Basophils	0.02	10^9/L	0	0.2
			Eosinophils	0.1	10^9/L	0	0.5
			Hematocrit	0.41	L/L	0.37	0.47
			Hemoglobin	140	g/L	125	163
			Lymphocytes	2.3	10^9/L	1	4.8
			Monocytes	0.6	10^9/L	0.3	1
			Neutrophils	1.3	10^9/L	1.8	7.7
			Platelets	211	10^9/L	150	350
			Erythrocytes	4.33	10^12/L	4.6	6.2
			Leukocytes	4.42	10^9/L	3.9	12.7

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Vital Signs - COVID-19								
Visit	**Visit Date (Study Day)**	**Date Collected (Study Day)**	**Record Identifier**	**Systolic Blood Pressure**	**Diastolic Blood Pressure**	**Respiratory Rate**	**Heart Rate**	**Oxygen Saturation**
COVID Illness Visit 1	22SEP2020 (9)	22SEP2020 (9)	1	131 mmHg	95 mmHg	26 breaths/min	111 beats/min	96 %
		23SEP2020 (10)	2	145 mmHg	94 mmHg	11 breaths/min	70 beats/min	95 %
		24SEP2020 (11)	3	120 mmHg	80 mmHg	20 breaths/min	83 beats/min	93 %
		25SEP2020 (12)	4	182 mmHg	72 mmHg	15 breaths/min	90 beats/min	97 %
		26SEP2020 (13)	5	118 mmHg	79 mmHg	16 breaths/min	80 beats/min	96 %

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

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Imaging									
Assessment Number	**Visit**	**Visit Date (Study Day)**	**Date of Assessment**	**Location of Assessment**	**If Other, Specify**	**Type of Imaging Exam**	**If Other, Specify**	**Overall Assessment**	**If Abnormal, Specify Findings**
1	COVID Illness Visit 1	22SEP2020 (9)	22SEP2020	CHEST		X-RAY	NA	ABNORMAL	Minimal bibasilar infiltrates

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	14SEP2020	
Withdrawn	VACCINATION	22SEP2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 1235 12351071, a 50-year-old white male with a height of 180.34 cm, a weight of 109.09 kg, and a BMI of 33.5 kg/m2, received Dose 1 on 14 Sep 2020. The subject had a reported medical history of asthma, hypertension, and allergic rhinitis (all since 2010); and dyslipidemia (since 2015). The central laboratory SARS-CoV-2 NAAT result was negative at Visit 1. The central laboratory N-binding antibody result was negative at Visit 1. On 22 Sep 2020 (Day 9), the subject was symptomatic of possible COVID-19 disease and was diagnosed with severe COVID-19, and experienced chills, a mild fever with a body temperature of 100.9 F°, myalgia, and pharyngitis and reported new or increased cough, new or increased muscle pain, new or increased shortness of breath, and new or increased sore throat, with the first symptom starting on 21 Sep 2020, 7 days after receiving Dose 1, and the last symptom resolved on 25 Sep 2020 (Day 12). He notified the investigator on 22 Sep 2020 (Day 9). The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 22 Sep 2020 (Day 9) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 22 Sep 2020 (Day 9) was positive. The subject had a telephone consultation (once). The subject went to the emergency room and was admitted to the intensive care unit on 22 Sep 2020 (Day 9) for further treatment. The subject was treated with remdesivir 200 mg intravenously (IV) (on 22 Sep 2020), which was later reduced to 100 mg IV (from 23 Sep 2020 to 26 Sep 2020). Additionally, he received ondansetron as needed (PRN) for nausea and acetaminophen PRN for pain. He remained afebrile throughout the hospitalization. On 22 Sep 2020 (Day 9), the subject had a heart rate of 111 beats per minute (bpm), blood pressure (BP) of 131/95 mmHg, respiratory rate of 26 breaths per minute, and oxygen saturation of 96%. On 23 Sep 2020 (Day 10), the subject had a heart rate of 70 bpm, BP of 145/94 mmHg, respiratory rate of 11 breaths per minute, and oxygen saturation of 95%. On 24 Sep 2020 (Day 11), the subject had a heart rate of 83 bpm, BP of 120/80 mmHg, respiratory rate of 20 breaths per minute, and oxygen saturation of 93%. On 25 Sep 2020 (Day 12), the subject had a heart rate of 90 bpm, BP of 182/72 mmHg, respiratory rate of 15 breaths per minute, and oxygen saturation of 97%. On 26 Sep 2020 (Day 13), the subject had a heart rate of 80 bpm, BP of 118/79 mmHg, respiratory rate of 16 breaths per minute, and oxygen saturation of 96%. The subject did not receive supplemental oxygen prior to or during the hospitalization. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19, admission to an intensive care unit, and oxygen saturation of ≤ 93%). On 22 Sep 2020 (Day 9), the chest x-ray showed minimal bibasilar infiltrates. The complete blood count, ferritin, and serum electrolytes were normal; however, C-reactive protein (CRP) was elevated at 13.5 mg/L (normal range [NR]: 0 - 9 mg/L) and fibrin D-dimer was normal at 365 ng/mL (NR: <500 ng/mL). The subject's CRP on 24 Sep 2020 (Day 11) returned to normal at 0.78 mg/L and the fibrin D-dimer remained normal at 296 ng/mL on 24 Sep 2020 (Day 11). The subject recovered from COVID-19 on 26 Sep 2020 (Day 13) and was discharged from the hospital. The subject was discontinued from the study intervention on 22 Sep 2020 since he no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 1971	49	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	94 kg	32.9 kg/m2	27SEP2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Obesity	Obesity	01NOV2019	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	27SEP2020 (1)	17:30
2	Placebo	15OCT2020 (19)	14:13

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Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	METAB	Hyperglycaemia	hyperglycemia	29OCT2020 (33)	12:00	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TC	N	Yes	NOT RELATED/OTHER: unknown	2	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	27SEP2020 (1)	27SEP2020 (1)	NASAL_SWAB	NEGATIVE
Visit 1	27SEP2020 (1)	27SEP2020 (1)	SERUM	NEGATIVE
Visit 2	15OCT2020 (19)	15OCT2020 (19)	NASAL_SWAB	NEGATIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	Yes	Yes

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Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 27OCT2020 (31)/ 26OCT2020 (30)/ 11NOV2020 (46)	NO		Asthenia
	YES	NEW LOSS OF TASTE OR SMELL	
	YES	NEW OR INCREASED MUSCLE PAIN	
	YES	NEW OR INCREASED SORE THROAT	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis: (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	27OCT2020 (31)	COVID-19 illness	27OCT2020 (31)	1	COVID-19

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SARS-COV-2 Test - Central Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Test Result
1	COVID Illness Visit 1	27OCT2020 (31)	27OCT2020 (31)	NASAL_SWAB	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	Visit	Visit Date (Study Day)	Date of Collection (Study Day)	Specimen Type	Specimen Collection Location
1	COVID Illness Visit 1	27OCT2020 (31)	27OCT2020 (31)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	Test Result	Comments/Findings/Details	Trade Name	Tradename Other (Specify)
1	POSITIVE		ATILA BIOSYSTEMS IAMP COVID-19 DETECTION KIT	

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Health Care Utilization					
Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	27OCT2020 (31)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA

Hospitalization Details
No Hospitalization Details

Respiratory Treatment
No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

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Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19								
Visit	Visit Date (Study Day)	Date Collected (Study Day)	Record Identifier	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate	Oxygen Saturation
COVID Illness Visit 1	27OCT2020 (31)	27OCT2020 (31)	1	140 mmHg	80 mmHg	20 breaths/min	125 beats/min	

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	27SEP2020	
Completed	VACCINATION	12NOV2020	
	FOLLOW-UP		

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Narrative Comment
Subject C4591001 4444 44442304, a 49-year-old white male with a height of 169 cm, a weight of 94 kg, and a BMI of 32.9 kg/m2, received Dose 1 on 27 Sep 2020 and Dose 2 on 15 Oct 2020 (Day 19). The subject had no reported medical history. The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. On 27 Oct 2020 (Day 31), the subject was diagnosed with severe COVID-19 and reported asthenia, new or increased muscle pain, and new or increased sore throat, with the first symptom starting on 26 Oct 2020, 11 days after receiving Dose 2, and at least 1 symptom ongoing as of the last available report. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 27 Oct 2020 (Day 31) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on 27 Oct 2020 (Day 31) was positive. The subject did not have any contact with nonstudy healthcare personnel. On 27 Oct 2020 (Day 31), the subject had a heart rate of 125 beats per minute (bpm), blood pressure of 140/80 mmHg, and respiratory rate of 20 breaths per minute. The subject therefore had severe COVID-19 illness per study protocol criteria (ie, confirmed COVID-19 and heart rate $\geqslant$ 125 bpm).

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